

Introduction to research for acupuncturists

Stephen Birch PhD

Affiliation: Kristiania University College, School of
Health Sciences, Oslo Norway

Practice: Amsterdam, the Netherlands (1998-present)

- Connecticut, USA (1995-1997)
- Boston, USA (1982-1995)

Research

Why do we need research

Why is research in acupuncture important?

Research on a therapy is done to understand how it might work (mechanisms) and whether it can help patients to improve or relieve certain symptoms (effectiveness)

Without research there is no evidence in favor of one treatment or another and then it becomes difficult to choose what treatment to give. This influences how patients are treated, the regulation of therapists and how or which treatments are paid for

Why is research in acupuncture important?

We do research to

- get more reliable data about what our treatments can do
- to help us improve what we do.
- To help learn about treating our patients as effectively as possible.
- to find out what works best in what cases
- To help develop new treatment methods and weed out ineffective or redundant methods
- to open the doors to hospitals, medical centers giving a wider access to a bigger segment of the population + to ensure growth and continued existence of the field
- for insurance coverage

Key research terminology

Clinical trial terminology

Double-blind – patient & practitioner do not know which treatment

Randomization – method ensuring random distribution between treatment groups

Placebo-controlled trial – patients are randomly assigned to the treatment OR a placebo treatment

Explanatory trial – a trial using randomization, double-blinding and comparing treatment to placebo treatment when the mechanism of the treatment is already known (e.g. drug)

Comparative effectiveness trial – trial comparing test treatment to an already established treatment – uses randomization, may use blinding (if comparing 2 drugs to each other)

Pragmatic trial – comparative effectiveness trial that tries to test treatment in actual practice

Key research terminology

Clinical trial terminology

Significant effects – when the statistical tests show that the treatment is more effective than chance than the comparison treatment (set at 1 in 20 or a ‘p-value’ of 0.05 or less)

Non-Significant effects – when the statistical tests show a p-value of greater than 0.05

Outcome – the main measurement of the symptom that is tested by the primary statistical testing (measurement tool or test for assessing e.g. pain, breathing capacity, depression, etc.)

Inclusion-exclusion criteria – criteria used for **including** patients in a trial (e.g. gender, presence of confirmed symptom, age range), and for **excluding** patients in a trial (e.g. presence of other health problems, age, mental capacity, use of medication, medical history)

Key research terminology

Clinical trial terminology

Sample size – the size of the included number of patients in a trial – needs to be sufficient to avoid making errors in the statistical tests and to be reasonably representative of the general population

Type I error – problem with a study leading to a false positive result in the statistical tests (e.g. insufficient sample size in a pragmatic trial)

Type II error – problem with a study leading to false negative result in the statistical tests (e.g. insufficient sample size in an explanatory trial)

Specific effect – treatment affect that can be attributed to the treatment being tested

Non-specific effect – clinical treatment effects due to the passage of time (e.g. regression to the mean) or other factors (e.g. chance) or to placebo

Significant problems
understanding this in
acupuncture trials

Key research terminology

Terminology

Evidence summaries terminology

Systematic review – systematic searches are employed to find all relevant studies on a topic, these studies are then evaluated for inclusion in the review. Included studies are evaluated together....a method for examining the evidence of a therapy in treatment of a condition with larger sample sizes

Meta-analysis – a method for doing a systematic review but where the outcome measurements are the same in all included studies thus allowing more specific statistical analysis of the data

Clinical Practice Guideline – a paper making recommendations about diagnosis and treatment of a problem for doctors (and often patients) after evaluating ALL the evidence related to diagnosing and treating that problem AND evaluating them side by side, specific criteria are needed for evaluating and presenting evidence (AGREE and GRADE)

Peer review – The process where experts critique a paper that has been submitted to a journal with comments that the authors have to address (including 'reject' because the study is bad)

Types of research

Types of research

- 1- Qualitative research
- 2- Laboratory investigations
- 3- Observational studies
- 4- Placebo controlled RCTs
- 5- No treatment RCTs
- 6- Standard practice RCTs
- 7- Meta-analyses / Systematic reviews
- 8- Health services research

Research

1- Qualitative research

relevant to patients, practitioners

Helpful to understand many different dimensions of the nature of practice, important in designing studies. Can include literature reviews, interviews, practitioner surveys, etc. Also can examine safety adverse effects of treatment.

It is of fundamental importance in developing an understanding of what is to be investigated by other (quantitative etc) methods, the theoretical and philosophical background of the practice system and for generating hypotheses to be tested in laboratory and clinical settings

2- Laboratory investigations

+ without knowledge of the mechanisms of a therapy no way to do placebo studies!

(basic research) - of theoretical/scientific relevance

Important to know **how** a treatment works.

Even if a treatment is shown to be effective but there is no acceptable description of how it works, the therapy is at risk of being rejected (as we see with homeopathy)

Laboratory investigations are essential for clinical research of acupuncture/TEAM - They assist in the development of an understanding of how treatment works and raise the credibility of the field **BUT**

these studies need to be more grounded in the theories of acupuncture/TEAM and actual clinical practice rather than capitulate to the expertise and limitations of the researchers and their methods

3- Observational studies

(outcomes research, before-after trials) - evaluating clinical significance

Very useful in clinical practice.

Includes '**clinical audit**' - examining outcomes on all patients that come into my practice with assessments before and after or examining all patients with a given condition that come into my practice or mine and my colleagues practices with assessments before and after.

Also can **examine safety and adverse effects** of treatment.

3- Observational studies

(outcomes research, before-after trials) - evaluating clinical significance

This is the simplest form of acupuncture study. **It is significantly under-utilised by the acupuncture field.** It can be used to gather data about what kind of conditions seem to respond to acupuncture treatment, what might be optimal treatments, etc.

Schools, practitioner organizations and individual or groups of practitioners can and should use this approach to enrich the field by creating a broad base of data that supports additional research

4- Placebo controlled RCTs

To examine specificity of treatment effects [also called explanatory trials]

does it make a difference where one places the needles?

Does it make a difference what techniques one applies?

This kind of trial attempts to test the theories of acupuncture that give rise to the specific treatment selected for that patient population. Also can examine safety adverse effects of treatment.

BUT

are they possible?

Can they test the 'explanatory model of TEAM'?

4- Placebo controlled RCTs

To examine specificity of treatment effects [also called explanatory trials]

We will come back to the difficult issue of placebo and placebo controls in a lot of detail

Unfortunately, despite all the evidence we are still forced to try to use 'placebo controlled' RCTs

5- No treatment RCTs

Also called 'pragmatic trial' - examines added value of treatment

Can examine safety & adverse effects of treatment.

How does treatment by acupuncture compare to not giving any treatment?

Are there additional things that can be applied with the acupuncture to make it more effective?

How safe is acupuncture?

5- No treatment RCTs

Also called 'pragmatic trial' - examines added value of treatment

This form of 'pragmatic trial' is a research approach that is at present under-utilized in acupuncture research

It can be a lot less difficult and expensive to perform than the more rigorous controlled trials and is amenable to participation of practitioners, schools and practitioner organizations with minimal consultation to academic/research experts

6- Standard practice RCTs

Comparison to existing treatment [also called pragmatic trials] e.g. comparison acupuncture to a specific drug for treatment of migraine

Also can examine safety adverse effects of treatment.

How well does acupuncture treat condition 'X' compared to usual treatment of that condition?

How cost effective is acupuncture compared to usual treatment for condition 'X'?

6- Standard practice RCTs

Does it make a difference how we apply the acupuncture treatment for condition 'X'?

Are there additional things that can be applied with the acupuncture to make it more effective?

Like the previous trial design, this form of 'pragmatic trial' is a research approach that is at present under-utilized in acupuncture research

6- Standard practice RCTs

It can be a lot less difficult and expensive to perform than the more rigorous controlled trials, but does need appropriate consultation to academic/research experts.

It is also amenable to participation of practitioners, schools and practitioner organizations

7- Systematic reviews/meta-analyses

Guides scientific acceptance, public health policy and public acceptance

Can also examine safety adverse effects of treatment.

What is the overall evidence for the effectiveness of acupuncture?

Should acupuncture be included in mainstream medical facilities?

Should acupuncture be paid for by national or private health insurance?

8- Health services research

informs payment decisions, practice guidelines [can include pragmatic trials]

Can also examine safety adverse effects of treatment.

How cost effective is acupuncture compared to usual treatment for condition 'X'?

8- Health services research

This form of 'pragmatic trial' is used by insurance companies, government reimbursement agencies to answer public health and social questions about the therapy
(do patients use less other services if they receive acupuncture?
does this save money?, etc)

This type of trial cannot answer questions about which patients benefit from treatment or whether a treatment is effective

Commonly accepted sequence of studies to test clinical effectiveness of a therapy (based on Sherman et al. 2002)

- 1- review clinical literature
- 2- consult practitioners and examine practitioner records
- 3- choose outcome measures
- 4- design/perform small uncontrolled trial ('phase I')
[including clinical audit]
- 5- design/perform small RCT ('phase II') [pilot a placebo-controlled trial]

Commonly accepted sequence of studies to test clinical effectiveness of a therapy (based on Sherman et al. 2002)

- 6- test feasibility of control (e.g. credibility) [pilot the sham acupuncture control]
- 7- design/perform full-scale 'explanatory' trial ('phase III')
[large scale placebo-controlled trial]
- 8- design/perform 'pragmatic' trial [comparative trial, e.g. acupuncture vs conventional therapy]
- 9- design/perform follow-on studies [e.g. modifying treatments to improve outcomes]

STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)

22 years ago at a research meeting in the UK we recognized that many acupuncture trials have issues with what treatment was delivered

Macpherson proposed developing guidelines that must be met for a trial of acupuncture to be published, we developed STRICTA from that discussion

The idea is that with publication requirements it would force researchers to pay attention to key issues that would improve what treatment was given

The first STRICTA was published in 2002 [MacPherson et al.]

The revised STRICTA version was appended to the CONSORT guidelines for any clinical trial in mainstream medicine in 2010 [MacPherson et al.]

Basic Format for Clinical Studies

For a study to be published in a 'peer-reviewed' journal the study usually needs to follow a certain structure

e.g. acupuncture versus a control treatment for condition X

Structure of papers include:

Abstract – really short summary of what was done, what found and implications etc.

Introduction – Usually starts with overview of condition X and overview of acupuncture, including evidence to date for acupuncture and X

Then needs to develop a rationale for why the study is being done, explaining the reasoning and prior evidence, leading to the study question

Basic Format for Clinical Studies

Methods – this describes the general type of trial used (Study Design **ALWAYS** should match the question)

It needs to describe the patient population and how they will be recruited

It must describe what measurement of X is to be used – the outcome - (and evidence for it's use)

It must describe the treatments – both details of the acupuncture and details of the control treatment

It must describe the randomization method used, how 'blinding' is to be done, the process of consent, who gave ethical approval for the study, how certain problems that come up are to be handled, etc.

It must describe how the statistical testing is to be done

It usually describes study personnel and their qualifications

Basic Format for Clinical Studies

Results – This is where the results of measurement of the primary and any secondary outcomes are presented both in summary, statistical and usually visual form

Discussion – the authors then summarise what was done, what they found and then proceed to discuss the implications of this relative to X, patients with X, acupuncture, medical care and can diverge into many different areas according to context

Conclusion – this presents a brief and succinct statement of what was done and what was found

References – no study can be done without adequate referencing
Different journals have different requirements for how references are presented and ordered

There is considerable evidence to date for some research questions with more limited evidence for other questions

We will briefly examine current evidence this afternoon

QUESTIONS?

Historical Traditions & Diversity of Zhen 鍼



Commentary

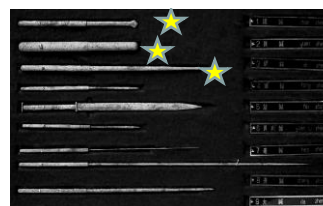
On defining acupuncture and its techniques: A commentary on the problem of sham

Stephen Birch^{a*}, Myeong Soo Lee^b, Tae-Hun Kim^c, Terje Alraek^d

‘Zhen’ emerged as a therapy in the Huangdi Neijing (circa 150BCE)

It began as a model of treatment that allows the practitioner to help ‘regulate the qi’ of the patient (Lingshu 75) by applying treatment to the newly described ‘jingmai’ (meridians) at specific locations ‘xue’ (acupoints) using metal tools ‘zhen,’ of which there were 9 (Lingshu 1)

Of these 9 ‘zhen’ two were not inserted and one possibly not,
Several were lightly inserted and several deeply so
(‘acupuncture’ is a mistranslation of the term ‘zhen’)



Historical Traditions & Diversity of Zhen 鍼

‘Zhen’ therapy was instituted in large part because the new theory of the Neijing proposed that since patients were not regulating their own qi by regulating their emotions (also by not eating well, regulating their lifestyle), they caused deficiency (xu) to occur which triggered/allowed problems to occur - the practitioner was needed to regulate the qi for them [Unschuld 2016]

This sounds like a simple theory but it is one that has always been profoundly loosely defined and is incredibly flexible – allowing for many interpretations and foci

In the Neijing the focus went to the ‘jingmai’ which are invisible (Lingshu 1) and to identify which is disturbed (excess/deficient) one needs to palpate the ‘mai’ (pulses) – but in the Neijing ‘pulse diagnosis’ is only emerging, it was systematised by the time of the Nanjing [Unschuld 1986]

Historical Traditions & Diversity of Zhen 鍼

BUT...for acupuncture and herbal medicine the diagnostic foci are naturally different so even though systematised in the Nanjing, it developed quite differently as herbal medicine started to utilise these theories and methods

A core focus was on the undefinable concept of ‘qi’ which already by the time of the Neijing was understood in quite different ways

From the beginning ‘zhen’ therapy was never uniform, different tools were described, locations and natures of the points and meridians were unclear and as they were made ‘clearer’ they changed and key foci like qi were understood VERY differently by different practitioners

Take the concepts of ‘xu-shi’ (deficiency-excess) and their treatment counterparts ‘bu-xie’ (tonification-drain)

The use of these concepts in the Neijing (circa 150 BCE) and the Nanjing (circa 100 CE) are quite different [Birch 2013]



Historical Traditions & Diversity of Zhen 鍼

Descriptions of needling techniques from the beginning (Lingshu 1) referred to the needling of the ‘superior’ physician’ (someone with enough training and experience to have figured out and understand how to work with qi) versus the needling of the ‘inferior physician’ (someone who just started, has little training or is experienced but has little interest in trying to master difficult skills)



This variation in needling is reflected in how 20th century practitioners in Japan and China resolved the problem of what can you teach beginners so that they can do something – will return to this

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 21, Number 1, 2015, pp. 1-7
© Mary Ann Liebert, Inc.
DOI: 10.1089/acm.2014.0207

Review Articles

Historical and Clinical Perspectives on *De Qi*:
Exposing Limitations in the Scientific Study of *De Qi*

Stephen Birch, PhD

Historical Traditions & Diversity of Zhen 鍼

There is no ONE set of theories for acupuncture

There is no ONE set of diagnostic methods or conclusions for acupuncture

There is no ONE way to needle in acupuncture

There ALWAYS has been many ideas, descriptions, methods and techniques

For example having to deqi ‘obtain qi’ with needling does NOT mean producing sensory stimulation with the needle (aching, throbbing, numbness etc) originally (and for many skilled practitioners today) it referred to very subtle things the practitioner feels ALSO....the needles do NOT HAVE TO BE INSERTED to be acupuncture or to be effective

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 21, Number 1, 2015, pp. 1-7
© Mary Ann Liebert, Inc.
DOI: 10.1089/acm.2014.0207

Review Arti

Historical and Clinical Perspectives on *De Qi*:
Exposing Limitations in the Scientific Study of *De Qi*

Stephen Birch, PhD

Artificial Life and Robotics
<https://doi.org/10.1007/s10015-020-00615-5>

ORIGINAL ARTICLE

The efficacy of a traditional Japanese acupuncture method, contact needle therapy (CNT), on peripheral blood flow of the skin

Keiko Ogawa-Ochiai¹, Takae Takebe^{1,2}, Mako Iwahashi¹, Akiko Shirai¹, Masaki Tsuda², Aya Komiya³, Keiichi Sugata¹, Osamu Tanno³

Received: 30 April 2020 / Accepted: 14 June 2020
© International Society of Artificial Life and Robotics (ISAROB) 2020

The role of touch in acupuncture treatment Acup in Med 2017

Younbyoung Chae,¹ Håkan Olausson²

Historical Traditions & Diversity of Zhen 鍼

IMPLICATIONS of this diversity for research

- Laboratory studies to investigate needling mechanisms have exposed important possible components but not yet focussed on what the historical literature and advanced practice say is important
- Also they have focussed on a limited range of needling techniques so there is little accepted evidence yet for other techniques
- AND.....clinical trial researchers think avoiding 'deqi' or avoiding 'needle insertion' is a good sham AND placebo treatment for clinical trials!!
- Clinical trials say they tested 'acupuncture' and draw their conclusions about whether 'acupuncture works' or not
- This is like testing an NSAID for pain and then concluding whether Western Medicine works for pain or not!!!

Researchers are still not aware of these problems

Developing research questions

This is VERY important but also quite difficult

In science we can NEVER PROVE something to be correct

We can ONLY DISPROVE its competing hypotheses

This is a peculiarity of the scientific method

Once we have articulated our hypothesis we can then formulate the question to be actually tested the 'research question'since we can only disprove something, the tested thing becomes the NULL HYPOTHESIS

We design studies to test this by using methods and statistical testing that allows us to conclude if the null hypothesis is correct or not

Developing research questions

If the *null-hypothesis* is found to be incorrect, then (following the logic of a double negative being a positive) the scientist then claims that they have found the *hypothesis* to be correct

If the *null-hypothesis* is found to be correct, then the scientist claims that they have found the *hypothesis* to be incorrect

For many areas of science, the mathematical testing (statistical tests) need to show a result that is robust (strong) – in clinical research the statistical tests need to reach significance (usually a **p-value** of less than 0.05)

For acupuncture.....due to the problems of defining and understanding what acupuncture is the failure or success of clinical trials **cannot** test the theories or basis of the practice of acupuncture [Birch, Lewith 2007]other research methods are needed to clarify these aspects to develop ‘testable hypotheses’ – more tomorrow

Developing research questions

The *hypothesis* needs to be framed in a way that can lead to a testable ‘*null-hypothesis*’

For example ‘does acupuncture treat tension headache pain?’ is a clinical question that is to be tested in a clinical trial

One can use a variety of study designs to start testing this question where the acupuncture treatment to be tested (needle these points with these techniques) is compared to different ‘comparison treatments’ e.g. to
 Sham/placebo treatment
 No treatment
 Standard treatment

We will look in more detail tomorrow at these different designs

Developing research questions

Once the study type has been selected and a measure of tension headache (outcome) has been selected patients are randomly assigned to one of the 2 treatment groups

The *hypothesis* becomes: 'Acupuncture treatment is more effective than the comparison treatment'

The *null-hypothesis* that the study **actually** tests is 'Acupuncture treatment is not more effective than the comparison treatment'

In order to answer this question correctly it is vital that all aspects are clear

The treatment to be tested is well defined

The outcome measure is clear (and validated)

Developing research questions

Developing a research question involves not only clarification and precision of the hypothesis....it also needs to be matched with the right resources to allow successful testing of the hypothesis

Examples:

Interested in what textbooks say about treatment of condition X

Requirements : access to sufficient quality textbooks and a

literature review

potential problem with establishing 'quality' textbooks

Interested in how practitioners treat condition X

Requirements : Design of a **questionnaire, survey** capable of capturing the relevant data about practitioner diagnoses and treatments for condition X

Potential problem: Access to a sufficient number of practitioners with experience treating X

Developing research questions

Interested in knowing if acupuncture is effective for condition X

Requirements : Finding and systematically searching databases for all relevant clinical trials &/or **systematic reviews/meta-analyses**

Having clear criteria for identifying which papers should be examined in your study

Having a systematic method of organising and critically analysing the data from the included papers

Need skills in reading clinical trials and reviews, and may need skills performing statistical analyses

Developing research questions

Interested in knowing if your acupuncture treatment is effective for condition X

Requirements: May need ethical approval from a research committee in order to proceed

need to guarantee safety of patient and safety of patient data, need peer-review that your method is capable of answering your question (if not expose patient to unnecessary potential harm)

Need systematic method of confirming patients have condition X (e.g. depression –DSM criteria)

Need systematic method of measuring X and change in X with treatment – need validated outcome measure (e.g. depression Beck or Hamilton depression scale)

Need sufficient time to perform the study

Usually need funding for such studies

Developing research questions

Interested in knowing what are practitioner diagnoses for condition X

Requirements: May need ethical approval from a research committee in order to proceed since you need to examine patient files or patients

Need systematic method of confirming patients have condition X (e.g. depression –DSM criteria)

Need systematic method of measuring X and change in X with treatment – need validated outcome measure (e.g. depression Beck or Hamilton depression scale)

Need sufficient time to perform the study

May need funding for the study

PICO

In recent years the process of performing scientific studies of patients has become more and more structured and organised. Following established guidelines helps ensure a more thorough and higher quality study.

One such method is **PICO**

P Population

I Intervention

C Comparison

O Outcomes

PICO

The PICO Principle assists you in organizing and focusing your question into a searchable query.

P

Participants / Population
Who are the relevant patients?

I

Intervention / Indication
What is the management strategy, diagnostic test or exposure that you are researching?

C

Comparator / Control
Is there a control or alternative management strategy, test, or exposure?

O

Outcome
What are the patient-relevant consequences?

PICO

Population

Who are the patients to be included in the study?

What symptoms or disease?

need formal confirmation of the presence of that

e.g. the ICHD-3 International Classification of Headache Disorders
for presence of tension headache

What severity and chronicity?

The severity and chronicity can be important criteria for
inclusion or exclusion in the study and needs to be assessed
using a valid scale

What age range?

The age range can be an important criteria for the inclusion
or exclusion in the study e.g. only 18-65

What other health problems?

Often studies exclude patients with certain diseases or
symptoms such as psychosis, heart disease, cancer

PICO

Population

What concurrent treatments?

The patient may be receiving a certain treatment that could
be required (inclusion criteria) or not wanted (exclusion
criteria) e.g. stroke rehabilitation where acupuncture is
used **ALONGSIDE** normal procedures **NEVER** instead of
them **OR** patient is on blood thinners and cannot be
included due to the risks of treatment

Which gender?

Obviously certain problems are limited by gender e.g.
menstrual-pregnancy – Women
prostate – men

but some symptoms could occur in both so it is necessary to
specify e.g. hot flashes in cancer treatment **ONLY** in men
knee OA only in women, etc.

so gender is often an inclusion/exclusion criterion

PICO

Intervention

Over time it has been a problem not clearly describing the treatment or administering it correctly, thus standards have been developed for doing this

One such standard is the CONSORT

CONSORT stands for Consolidated Standards of Reporting Trials and encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials.

[<https://www.consort-statement.org/>]

This standard needs to be met if you want to publish in a good journal

It therefore forces researchers to attend to and deal with all the issues raised in its' 25 item checklist

This not only improves the quality of trials but helps ensure better more consistent, reproducible treatments

PICO

Intervention

But for acupuncture.....until the STRICTA guideline was developedit was routine for inadequate or inappropriate or unsubstantiated treatments to be given in a trial when the acupuncture gives their own idiosyncratic treatment &/or is poorly trained

In a 1992 review of 32 chronic headache, back pain and neck pain trials I found NONE had delivered a core amount of treatment (at least 10 needles at least 10 times) [Birch 1992, 1997]

When I relaxed the standard to at least 6 needles at least 6 times half met the minimum criteria for adequate treatment

When Berman included these criteria in his review of acupuncture for chronic pain he found a correlation between this adequate treatment and better outcome [Ezzo et al. 2000]

But setting standards for 'adequate treatment' is complex [Stux, Birch 2001]

PICO

Intervention

Since STRICTA the problem of sufficient acupuncture treatment has improved BUT not gone away

One issue is what are the qualifications and experience of the therapist

Thus it is routine to insist that the therapist has a certain amount of training, has practised for a minimum amount of time and has enough experience treating the problem that is to be treated in the trial

This is an ongoing issue – e.g. physios who do 100 hour courses and practice ‘acupuncture’; having students of acupuncture perform treatment in clinical trials.....

Intervention

PICO

For trials of acupuncture the following are seen in STRICTA as important and need to be addressed in the trials

- (1) **Acupuncture rationale** (1a) Style of acupuncture (1b) Reasoning for treatment provided, based on historical context, literature sources and/or consensus methods, with references where appropriate (1c) Extent to which treatment was varied
- (2) **Details of needling** (2a) Number of needle insertions per subject per session (2b) Names (or location if no standard name) of points used (uni-/bilateral) (2c) Depth of insertion, based on a specified unit of measurement or on a particular tissue level (2d) Responses sought (eg, *de qi* or muscle twitch response) (2e) Needle stimulation (eg, manual or electrical) (2f) Needle retention time (2g) Needle type (diameter, length and manufacturer or material)
- (3) **Treatment regimen** (3a) Number of treatment sessions (3b) Frequency and duration of treatment sessions
- (4) **Other components of treatment** (4a) Details of other interventions administered to the acupuncture group (eg, moxibustion, cupping, herbs, exercises, lifestyle advice) (4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients
- (5) **Practitioner background** (5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice)

PICO

Intervention

The history and nature of acupuncture practice is also important

Assumptions about what is acupuncture and ignorance of the history and diversity can lead to incorrect assumptions that weaken or harm the study – more details tomorrow in discussions of study designs

BUT...given the huge range of methods and styles of acupuncture treatment just saying 'acupuncture' is convenient BUT imprecise It is better if researchers started specifying which type of treatment is tested so that if it fails it does not drag down other styles of treatment with it

Whatever treatment is given in the tested treatment, it needs to be described in enough detail so that it is reproducible by others
Many researchers publish separate paper with these details

PICO

Comparison

Earlier I mentioned about the usual sequence for testing a therapy
By the time you get the phase II trials and later trials, it is necessary to have a comparator treatment so that the tested treatment is compared to placebo, standard therapy etc.

design/perform small RCT ('phase II')

If needed test feasibility of control (e.g. credibility)

design/perform full-scale 'explanatory' trial ('phase III')

design/perform 'pragmatic' trial

design/perform follow-on studies

On this STRICTA describes:

(6) Control or comparator interventions (6a) Rationale for the control or comparator in the context of

PICO

Comparison

The choice of comparator intervention depends of the study question

If you need to show that THIS SPECIFIC treatment (e.g. a chemical substance) can have specific clinical effects beyond placebo you need to use a placebo controlled trial

For acupuncture since treatment is not a chemical substance rather a procedure or technique this comparator treatment is called 'sham' which is a kind of fake therapy not intended to do anything clinically relevant but which looks the same so patients cannot tell what treatment they received

This is done IN ORDER to control for placebo effects

MORE on this tomorrow

BUT simply saying we compared acupuncture to sham acupuncture is not enough....more needs to be done

PICO

Comparison

At the very least a pilot study should be done to see what the sham technique might do

AND

It is important to verify that blinding worked – this is usually done by assessing the credibility of the treatment which can involve asking patients whether they think they received the test acupuncture or the sham acupuncture

AND

If the intent is to truly control for placebo effects a number of additional procedures are required [Birch 1997, Birch 2004]

Which we will see tomorrow that no one uses these

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 10, Number 3, 2004, pp. 481-498
© Mary Ann Liebert, Inc.

Clinical Research on Acupuncture: Part 2. Controlled Clinical Trials, an Overview of Their Methods

STEPHEN BIRCH, Ph.D., Lic.Ac. M.B.Ac.C.

PICO

Comparison

If the question is about whether acupuncture is a useful addition to what is usually done to a patient (e.g. medication, procedure) or whether acupuncture is as or more effective than the usual treatment, then the comparator treatment is the standard or usual treatment (e.g. medication, physiotherapy procedure, etc.)

MORE details tomorrow

Details about that selection are described in Birch 2004

The usual treatment also

needs to have been

tested and shown

effective compared to

placebo

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 10, Number 3, 2004, pp. 481-498
© Mary Ann Liebert, Inc.

Clinical Research on Acupuncture: Part 2. Controlled Clinical Trials, an Overview of Their Methods

STEPHEN BIRCH, Ph.D., Lic.Ac. M.B.Ac.C.

PICO

Comparison

Whichever comparator treatment is chosen/developed, it needs to be described in sufficient details so that it can be reproduced by others

Many researchers publish another paper with details, rationale, evidence, references etc. for the interventions

PICO

Outcomes

For every symptom that is studied it is VITAL that there is a good measurement of that symptom that can be applied at different time points to capture change over time of the symptom

	treatment time →			
1-baseline	2-mid	3-end	4-follow up	
Before	often	always	commonly done	
treatment	done	after	at certain times	
begins	during	treatment	after treatment	
	middle	finishes	finishes	
	of treatment		such as 3-/6-month	

PICO

Outcomes

The measured outcome needs to be specific for the symptom and becomes the **primary outcome** upon which the principle statistical testing is done

It needs to be valid, reliable, dependable and precise

For different health problems different scales, tools, questionnaires, tests, scans etc. are done

Each needs to be tested to show it is relevant to the symptom (validity)

Each needs to be tested to show that it is repeatable and consistent (reliability)

The science of developing medical tools or questionnaires etc. for measurement of health in research is part of the field of **biometrics**

PICO

Outcomes

To assess the degree of depression that someone has you would probably first use the DSM V criteria to confirm the presence and relative degree of the depression

For the outcome you may choose to use a depression questionnaire such as the Beck or Hamilton

EVERY question, the grading of answers on the question and the complete set of questions and answers to yield a score (degree of depression) has been subjected to various studies in order to guarantee accuracy and validity

The same process is used in mechanics, engineering, biochemistry

The tiniest error could cause the plane to crash

The tiniest error can give a false reading in biochemical measurements

This is important across all practical science disciplines

Evidence for effectiveness of acupuncture

Where to find evidence? Where can you find clinical trials of acupuncture, laboratory studies of acupuncture, reviews of acupuncture?

Scientific studies are published in peer-review journals

Methods for performing each kind of study have been developed and publicised

Journals have editorial teams that should cover the required expertise in their areas of interest who perform the 'peer-review' for a submitted study

These journals are listed in different on-line databases

The higher quality the journal (e.g. citation index) the more difficult to get published in the journal and the more dependable the paper that is published in the journal

Evidence for effectiveness of acupuncture

Major on-line databases that can be accessed are:

Pubmed / Medline see: <https://pubmed.ncbi.nlm.nih.gov/>

For free – easiest to access and use

Embase see: <https://www.embase.com/>

Need to join

AMED see: <https://www.ebsco.com/products/research-databases/allied-and-complementary-medicine-database-amed>

Need to join

Within different countries there are also specific databases in their language, in e.g. China, Japan, Korea

Searching databases thoroughly and systematically for all publications on a topic usually requires the assistance of an expert, a library specialist etc.

BUT once you find a reference, for many papers you need to have paid access to the journal to access the paper

Evidence for effectiveness of acupuncture

Thousands of clinical trials of acupuncture have been conducted with hundreds of systematic reviews/meta-analyses published evaluating these trials [Ma et al. 2016, Birch et al. 2018, Janz, McDonald 2017]

Evidence of acupuncture being effective has emerged for more than 100 symptoms [Janz, McDonald 2017, Birch et al. 2018, Hempel et al. 2014]

But the strength of the evidence is generally weak-moderate & for most areas where evidence exists: more studies are needed +/- or higher quality studies are needed to permit definitive statements of effectiveness

As this evidence has emerged, increasing numbers of expert groups have recommended acupuncture as treatment across a growing list of conditions [Birch et al. 2018]

Evidence for effectiveness of acupuncture

Number of review articles clearly show that acupuncture is more effective than sham

PREDICTED by virtue of using active treatment as sham -creating apparent weak effects as an artifact

And as or at times more effective than regular medical treatments


BUT
GENERALLY
WEAK
EFFECTS

Lewith, Machin 1983, Birch 1997, Birch et al. 2002, Birch 2004, Birch 2006, Lund et al. 2009, Lundeburg et al. 2011, Birch et al. 2016, Appleyard et al. 2014, Birch et al. 2021,

For a large number of symptoms/conditions
PAIN

GENERALLY
MODERATE
EFFECTS -
MORE
ACCEPTABLE

Acupuncture for Chronic Pain

Individual Acupuncture for Chronic Pain: Update of an Individual Patient D. **PAIN** 

Andrew J. V
Hugh MacP
Klaus Linde

Andrew J. Vi
Nadine E. Fo
Klaus Linde⁵⁵ **The persistence of the effects of acupuncture after a course of treatment: a meta-analysis of patients with chronic pain** 2022

H. MacPherson^{1*}, E.A. Vertosick², N.E. Foster², G. Lewith³, K. Linde⁴, K.J. Sherman¹, C.M. Witt^{5,6,7}, A.J. Vickers⁸,
On behalf of the Acupuncture Trialists' Collaboration

Evidence for effectiveness of acupuncture

The Acupuncture Evidence Project

A Comparative Literature Review

BEST (MODERATE) EFFECTS

Chronic back pain,
Tension headache,
Migraine,
Knee osteoarthritis,
Post-op pain
PONV,
CINV,
Allergic rhinitis

John McDonald
Stephen Janz

January 2017
(Revised Edition)

Australian
Chinese
Medicine
Association

Evidence for effectiveness of acupuncture

WEAK EFFECTS

For a number of other pain conditions including

Neck pain, acute low back pain, fibromyalgia, chronic pain, tennis elbow, sciatica, shoulder pain, TMD, Shoulder impingement syndrome (early stage) (with exercise), Plantar heel pain,

Cancer related pain, aromatase inhibitor related arthralgia, Cancer-related fatigue,

Dysmenorrhea, labour pain, Menopausal hot flushes, prostatitis pain/chronic pelvic pain syndrome,

Acute stroke, Post-stroke insomnia, Post-stroke shoulder pain, Post-stroke spasticity, Stroke rehabilitation

Anxiety, Depression (with antidepressants), Insomnia, PTSD, Schizophrenia (with antipsychotics), Perimenopausal & postmenopausal insomnia, IBS, Asthma in adults, Constipation, Dry eye, Hypertension (with medication), Obesity, Restless leg syndrome, Smoking cessation (up to 3 months), Ambulatory anaesthesia, Craniotomy anaesthesia, Recovery after colorectal cancer Resection, Modulating sensory perception thresholds,

The Acupuncture
Evidence Project
A Comparative Literature Review

John McDonald
Stephen Lauz
January 2017
(Revised Edition)

Evidence for effectiveness of acupuncture

For a decent compilation of symptoms and references to published review articles in addition to

The Acupuncture
Evidence Project

A Comparative Literature Review

John McDonald
Stephen Lauz

January 2017
(Revised Edition)

Appendix 1

See:

Positive or Trend Positive Conclusions in Favor of the Effectiveness for Acupuncture from Reviews of the Clinical Trial Literature

	No	Conditions	References
REVIEW ARTICLES	1	Achilles tendinopathy	Cox et al. ^{A1}
	2	Alcohol dependence	Shin et al. ^{A2} , Southern et al. ^{A3}
APPENDIX 1. (CONTINUED)			
Overview	No	Conditions	References
Guidelines	92	Stroke rehabilitation	McDonald and Janz, ^{A6} NIH, ^{A26} Monckton et al., ^{A99} Kong et al., ^{A149} Li et al., ^{A263} Li et al., ^{A264} Lim et al., ^{A265} Liu et al., ^{A266} Vados et al., ^{A2} Wu et al., ^{A268} Xin et al., ^{A269} Yang et al., ^{A270} Zhang et al., ^{A271} Zhao et al. ^{A272}
	93	Tennis elbow	McDonald and Janz, ^{A6} NIH, ^{A26} Ernst and Lee, ^{A36} Buchbinder et al., ^{A2} Chang et al., ^{A274} Gadau et al., ^{A275} Trinh et al., ^{A276}
A Bibliography	94	Tension headache	McDonald and Janz, ^{A6} Hempel et al., ^{A11} Lee et al., ^{A13} NIH, ^{A26} Dalamagka, ^{A34} Hopton and Macpherson, ^{A39} Saramago et al., ^{A47} Vickers et al., ^{A50} Yin et al., ^{A52} Lee and Ernst, ^{A81} Tait et al., ^{A104} Sun and Gan, ^{A195} Linde et al., ^{A277} Linde et al.
	95	Tinnitus	Liu et al. ^{A279}
	96	Temporomandibular joint dysfunction	McDonald and Janz, ^{A6} Hempel et al., ^{A11} Birch et al., ^{A30} Yuan et al., ^A Roberts and Moore, ^{A102} Tait et al., ^{A104} Cho and Whang, ^{A280} Jung et al., ^{A281} LaTouche et al., ^{A282} List and Axellson, ^{A283} Rosted ^{A284}

Evidence for effectiveness of acupuncture

STRONGEST EVIDENCE is for:

Chronic pain including

back pain, neck pain, tension headache, migraine, knee osteoarthritis, aromatase inhibitor arthralgia, post-op pain

Comparative effectiveness of acupuncture in sham-controlled trials for knee osteoarthritis: A systematic review and network meta-analysis

Non-pain conditions including

PONV, CINV

Allergic rhinitis

Boram Lee¹, Tae-Hun Kim², Stephen Birch³, Terje Alraek^{1,4}, Hye Won Lee⁵, Arya Nielsen⁶, L. Susan Wieland⁷ and Myeong Soo Lee^{1*}

frontiers | Frontiers in Medicine

Some consider the evidence quite good for:

Cancer related fatigue, depression, anxiety, cancer related pain, pregnancy related pelvic-back pain,

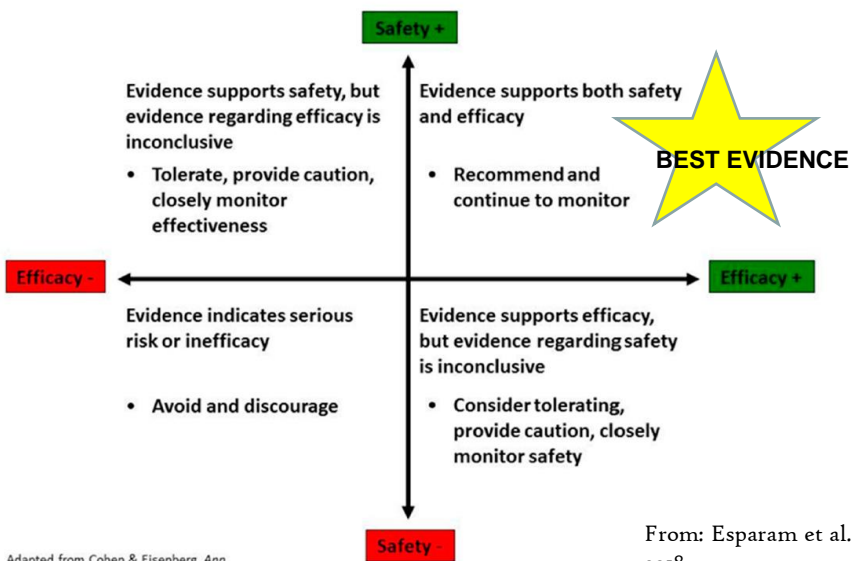


Systematic Review

Acupuncture for Managing Cancer-Related Fatigue in Breast Cancer Patients: A Systematic Review and Meta-Analysis

Tae-Young Choi¹, Lin Ang¹, Ji Hee Jun¹, Terje Alraek^{2,3}, Stephen Birch³, Weidong Lu⁴ and Myeong Soo Lee¹

Evidence Assessments and Therapy Recommendations



Adapted from Cohen & Eisenberg, *Ann Intern Med.* 2002;16:136(8):596-603

Evidence & reasons for recommending acupuncture

It has a **strong safety record** [Lytle 1993, MacPherson 1999, Vincent 2001, Vickers et al. 2002, Birch et al. 2004, White 2004, Yamashita, Tsukuyama 2008, Witt et al. 2009, MacPherson, Hammerschlag 2012, Birch et al. 2013, Wu et al. 2015, McDonald, Janz 2017, Chan et al. 2017] - Especially when delivered by qualified practitioners

&

It has **evidence of cost-effectiveness** for some conditions (McDonald, Janz 2017)

&

It has **some (weak or moderate) positive evidence of effectiveness**

&

Other candidate therapies have same levels of evidence &/or same evidence but more adverse effects

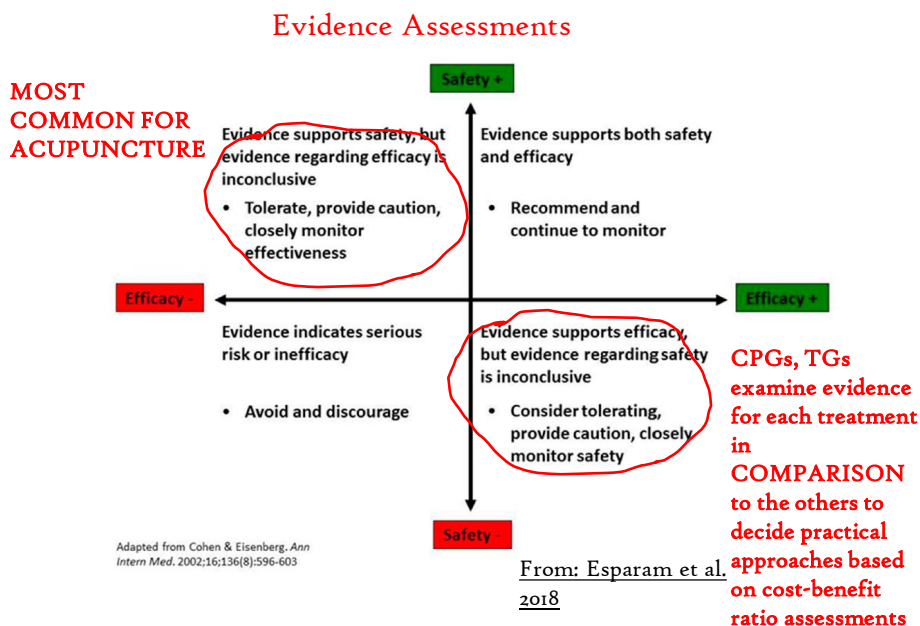
OR

Other candidate therapies have stronger evidence but high risk adverse effects

&/or

Patient wants to try acupuncture (patient preference is given greater weight)

(e.g. Shared Decision Making process)



Recognition of the evidence of effectiveness of acupuncture

Treatment recommendations are made in ‘Practice Guidelines’

Pubmed Mesh term for ‘Practice Guideline’

“Work consisting of a set of directions or principles to assist the health care practitioner with patient care decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances. Practice guidelines may be developed by government agencies at any level, institutions, organizations such as professional societies or governing boards, or by the convening of expert panels”

[accessed July 18, 2022: <https://www.ncbi.nlm.nih.gov/mesh/68017065>]

We broke this down into the more technical guideline ‘Clinical Practice Guideline’ (CPG) and the less formal ‘Treatment Guideline’ (TG) [Birch et al. 2018]

Recognition of the evidence of effectiveness of acupuncture

CPGs are supposed to follow strict rules for data gathering, data analysis, data assessment, presentation and so on (AGREE, GRADE etc.)

They are published on-line through professional organisations e.g.

UK – NICE, SIGN (National Institute of Health and Care Excellence & Scottish Intercollegiate Guideline Network)

Germany – AWMF (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften)

Denmark – Sundhedsstyrelsen (Danish National Board of Health and Welfare)

Or they are published in medical journals

They present scientific data and recommendations based on that using technical language

Recognition of the evidence of effectiveness of acupuncture

TGs are less technical and need to be written for the public who may not read well or understand technical terms [NHMRC 2000] and comprise the largest number we have found

CPGs are technical documents often too difficult for patients to read or difficult to access

TGs are simpler documents focussing on clear language statements easier for the patient to read and readily accessible, often as webpages on advisory group websites (e.g. UK NHS websites, US oncology websites - American Society of Clinical Oncology, ASCO)

Writing simpler language summaries assists with guideline implementation. Many are produced by or supported by Government, Department of Health groups and so on



Recognition of the evidence of effectiveness of acupuncture

Given that only the most effective therapies should be recommended in CPGs, TGs, why might acupuncture be recommended?

DIFFICULT question....but can suggest few reasons

1- the evidence for acupuncture is now good enough that it should be used as a first line treatment e.g. chronic low back pain: [AHRQ 2016, Qaseem et al. 2017 - American College of Physicians]

2- evidence for any therapy for a particular condition is poor, but acupuncture has some evidence of effectiveness & it is a safe therapy e.g. Palliative care: [Birch et al. 2020]

3- the evidence for acupuncture is as good as or slightly less than for other therapies for the condition, but it is safer e.g. chronic primary pain : [NICE 2021]

Recognition of the evidence of effectiveness of acupuncture

Given that only the most effective therapies should be recommended in CPGs, TGs, why might acupuncture be recommended?

4- acupuncture has some evidence of effectiveness for a particular chronic condition and given the need to engage the patient more in their treatment it is better to respect patient wishes, Shared Decision Making is a process to facilitate and support patient participation and their wishes

e.g. knee and hip osteoarthritis, depression, stop smoking: [NHS England 2017]

5- acupuncture can help other symptoms within the symptom cluster associated with a symptom and thus offer a unique treatment option e.g. in cancer patients: [Thompson, Johnstone 2016, Birch et al. 2019]

Recognition of the evidence of effectiveness of acupuncture

I and my colleagues have been searching for CPGs and TGs since 2013.

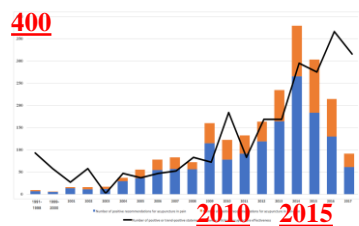
In 2018 we presented our findings as of August 31, 2017

We had found **1,311** publications making **2,189** positive recommendations.

1,486 were related to **107** pain indications and **703** were related to **97** non-pain indications

The search also revealed **96** symptoms/conditions with at least one positive review article

The following graphic shows the growth of number of review articles (line) and recommendations to use acupuncture (bars) over time



THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 24, Number 8, 2018, pp. 732-739
© Mary Ann Liebert, Inc.
DOI: 10.1089/acm.2018.0902

JACM

REVIEW ARTICLES

Overview of Treatment Guidelines and Clinical Practical Guidelines That Recommend the Use of Acupuncture: A Bibliometric Analysis

Stephen Birch, PhD¹, Myeong Soo Lee, PhD², Terje Alraek, PhD^{3,4} and Tae-Hun Kim, PhD⁴

Recognition of the evidence of effectiveness of acupuncture

Since that paper was published we have published several more papers summarising evidence and number of recommendations for use of acupuncture in:

General health
(health improvement) [Birch 2018]



Review Article
**Treating the patient not the symptoms:
Acupuncture to improve overall health – Evidence,
acceptance and strategies**

Stephen Birch
Kristiansia University College, Department of Health Sciences, Oslo, Norway

Back pain [Birch 2019]
Centers for Medicare and Medicaid Services
<https://www.cms.gov/medicare-coverage-database/staticpages/public-comment.aspx?commentID=31450&ReportType=nca>



Review Article
**Evidence, safety and recommendations for when to use acupuncture
for treating cancer related symptoms: a narrative review**

Stephen Birch^{1,2*}, Myeong Soo Lee³, Terje Alraack^{4,5}, Tae-Hun Kim⁶
¹Department of Health Sciences, Kristiansia University College, Oslo, Norway
²Clinical Methods Division, Eastern Institute of Oriental Medicine, Daejeon, Republic of Korea
³National Research Center in Complementary and Alternative Medicine, Faculty of Medicine, Department of Community Medicine, Ulsan University of Medicine, Ulsan, Republic of Korea
⁴University of Bamberg, Bamberg, Germany
⁵Central Hospital, Kangbuk Samsung Hospital, Seoul, Republic of Korea

Oncology [Birch et al. 2019]

Recognition of the evidence of effectiveness of acupuncture

Palliative care
[Birch et al. 2020]

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 26, Number 9, 2020, pp. 786-793
© Mary Ann Liebert, Inc.
DOI: 10.1089/acam.2020.0032

JACM

**Acupuncture as a Treatment Within Integrative
Health for Palliative Care:
A Brief Narrative Review of Evidence
and Recommendations**

Stephen Birch, PhD¹, Mark Bovey, MSc², Terje
Tae-Hun Kim, PhD³ and Myeong Soo Lee, PhD

European Journal of Integrative Medicine 000 (2021) 161207



Opinion Paper
**Acupuncture for chronic primary pain – are UK guidelines now consistent
with other countries?**

Stephen Birch^{1,2*}, Mark Bovey³, Nicola Robinson^{4,5}
¹Kristiansia University College, School of Health Sciences, Oslo, Norway
²British Acupuncture Council, London, United Kingdom
³School of Health and Social Care, London South Bank University, United Kingdom
⁴Centre for Evidence-based Chinese Medicine, Beijing University of Chinese Medicine, Beijing

Chronic pain [Birch et al. 2021]

Stroke
[Birch, Robinson 2022]

Phytomedicine 104 (2022) 154297



Review article
**Acupuncture as a post-stroke treatment option: A narrative review of
clinical guideline recommendations^{2*}**

Stephen Birch¹, Nicola Robinson^{2,3,4*}



Review Article
**Shoulder Pain and the Potential Role of
Acupuncture: A Narrative Review of Clinical
Practice and Treatment Guidelines**

Stephen Birch^{1,*}, Myeong Soo Lee², Tae-Hun Kim³, Terje Alraack^{1,4}

Shoulder pain [Birch et al. 2022]

Recognition of the evidence of effectiveness of acupuncture

In early 2019 I received some funding from the British Acupuncture Council to establish an online database for the data

This project is on hold since the pandemic while we seek more funding and a host for the website

Current projects include

Comparison of official CPGs in UK and Germany (with Alraek, Lee, Kim and others)

Comparing statements in CPGs about acupuncture published in the UK (NICE and SIGN) and Germany (AWMF)

Recommendations to use acupuncture within TGs by the Australian Government (with McDonald, Zaslowski, Zheng, Alraek, Lee and Kim)

Presenting the (extensive) data of statements about use of acupuncture made by Australian National and State Government websites

Starting to organise the data in paediatrics (with Alraek, Lee, Kim and others)

For a narrative review probably similar to the Oncology, Palliative Care and Shoulder pain papers

Recognition of the evidence of effectiveness of acupuncture

What are the current numbers of statements in CPGs and TGs recommending for and against acupuncture?

As of January ??, 2023

*A total of **9,340** positive recommendations for acupuncture from **3,809** different publications have been found*

***5,572** recommendations for the use of acupuncture for **223** pain indications from around the world*

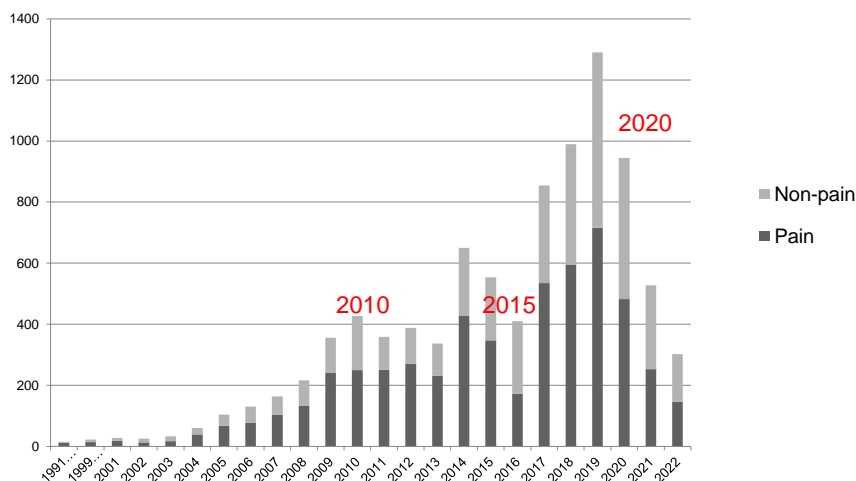
And

***3,768** recommendations for the use of acupuncture for **315** non-pain indications from around the world*

Recognition of the evidence of effectiveness of acupuncture

TREATMENT GUIDELINE RECOMMENDATIONS:

By year of publication



Recognition of the evidence of effectiveness of acupuncture

What are the current numbers of statements in CPGs and TGs recommending for and **against** acupuncture?

As of September 25, 2022

*A total of **402** negative recommendations for acupuncture from **316** different publications have been found*

***178** recommendations against the use of acupuncture for **40** pain indications from around the world*

And

***224** recommendations against the use of acupuncture for **88** non-pain indications from around the world*

Recognition of the evidence of effectiveness of acupuncture

What are the current numbers of statements in CPGs and TGs recommending for and against acupuncture?

Recommendations not to use acupuncture are rarely definitive 'do not use' acupuncture statements (like NICE 2014 with OA and NICE 2016 with back pain)

They are almost all statements about the inadequacy of evidence to formulate recommendations to use or not use acupuncture, thus it cannot be recommended one way or another

Recognition of the evidence of effectiveness of acupuncture – TOP 20

Nr Rx	Condition	National CPGs	Australian Govt TGs
566	Low back pain	GER/UK/US/CAN	yes
391	Chronic pain	GER/UK/US/CAN/NZ/AUS	yes
427	CINV (chemo-nausea & vomiting)	GER/UK/US/CAN/NZ/AUS	yes
402	cancer related pain;	GER/UK/US/CAN/NZ/AUS	yes
393	Migraine	GER/UK/US/CAN/NZ/AUS	yes
282	Knee OA	GER/UK/US/CAN/NZ/AUS	yes
321	Tension headache;	GER/UK/US/NZ/AUS	yes
282	Neck pain;	GER/UK/US/CAN/NZ/AUS	yes
222	PONV (post-op nausea & vomiting)	GER/UK/US/CAN/NZ/AUS	yes
152	Alcohol/drug dependence/misuse	UK/US/NZ	yes
171	post-op pain	GER/US/NZ/AUS	yes
226	Fatigue in cancer;	GER/UK/US/CAN/NZ/AUS	yes
177	Fibromyalgia;	GER/UK/US/CAN/NZ/AUS	yes
207	oncologically related hot-flashes;	GER/UK/US/CAN/NZ/AUS	yes
190	Anxiety;	UK/US	
157	Depression;	UK/US/CAN	yes
123	joint pain/arthritis pain;	GER/UK/US/CAN/NZ	yes
96	Hip OA;	GER/US/CAN/NZ	yes
111	Morning sickness;	UK/US/CAN/NZ/AUS	yes
109	Insomnia	GER/UK/US/AUS	yes

Recognition of the evidence of effectiveness of acupuncture

Examples of recommendations for the use of acupuncture

The case of Australia (working with John McDonald, Chris Zaslowski, Zhen Zheng, Terje Alraek, Myeong Soo Lee and Tae-Hun Kim)

In the late 1990s the Australian Government Department of Health made a decision to develop a greater on-line internet presence to provide easy to read publications for the general public

The Victorian Government established the Better Health channel in 1999

The National Government established Health Direct and Cancer Australia in 2006

Often the webpages make statements about treatment options and give links for additional information

For example the 2022 Health Direct webpage on acupuncture lists several chronic pain indications that acupuncture can be used for then refers to a few international webpages (e.g. UK NHS) and then refers to dozens of trusted webpages (with links) that make statements about acupuncture

Recognition of the evidence of effectiveness of acupuncture

The Health Direct 2022 (Australia) webpage includes statements for and against acupuncture for **114** different health problems

Statements recommending acupuncture for **95** different symptoms

Statements recommending not to use acupuncture for **28** different symptoms

With an overlap of **9** positive and negative statements within the **28**, showing mixed opinions on those **9**

This is from a single webpage on acupuncture published on behalf of the Australian Government Department of Health

Recognition of the evidence of effectiveness of acupuncture
HOW MANY RECOMMENDATIONS ABOUT THE USE OF ACUPUNCTURE HAVE BEEN MADE BY DANISH HEALTH AUTHORITIES?

I may have missed publications since my searching is done primarily in English....but to date I have found the following:

The Sundhedsstyrelsen has recommended acupuncture for the following

Cancer pain (2012)
 Low back pain (including acute low back pain) (2018, 2019)
 Neck pain (including acute neck pain) (2016, 2018, 2020)
 Tension headache (2018)
 migraine (2018)
 knee osteoarthritis (2018)
 fibromyalgia (2018)
 pregnancy related back/pelvic pain (2001)

And against acupuncture for the following:

Stroke rehab (2012)
 Lumbar related radiculopathy (2016)
 Cervical radiculopathy (2016, 2018)

Recognition of the evidence of effectiveness of acupuncture
HOW MANY RECOMMENDATIONS ABOUT THE USE OF ACUPUNCTURE HAVE BEEN MADE BY DANISH HEALTH AUTHORITIES?

In 2016 the Danish cancer society (Kraeftens Bekaempelse) recommended acupuncture for:

Cancer pain + neuropathic pain,
 Nausea and vomiting due to chemotherapy or radiotherapy
 Hot flashes,
 Improved quality of Life in cancer,
 Dyspnoea, mucositis, pruritis and hiccups in palliative care,

Altogether....20 recommendations for acupuncture
3 against acupuncture

How many of these recommendations did you already know about?

If you don't know about these official publications by Danish medical experts about acupuncture....how can your acupuncture association create strategies to promote acupuncture to take advantage of them?

Recognition of the evidence of effectiveness of acupuncture

What about other Scandinavian countries?

So far I have found the following:

	Norway	Sweden	Finland
Low back pain	2007	2000, 2007	2008, 2017, 2022
Neck pain		2015	
TMD	2018	2013	2013
Knee OA			2014
Hip OA		2012	
Tennis elbow			2013
Labour pain	2013		
Cancer pain	2016, 2017		
Cancer related			
Hot flashes	2016		
Urinary incontinence			2011
Breast Engorgement	2019		
Breast discomfort			
with breast feeding	2019		
Facilitate breastfeeding	2019		

How might acupuncture work?

A lot of studies have been done investigating how acupuncture might work

Almost all have focussed on questions like:

What mechanisms might be triggered for acupuncture to be able to reduce e.g. pain?

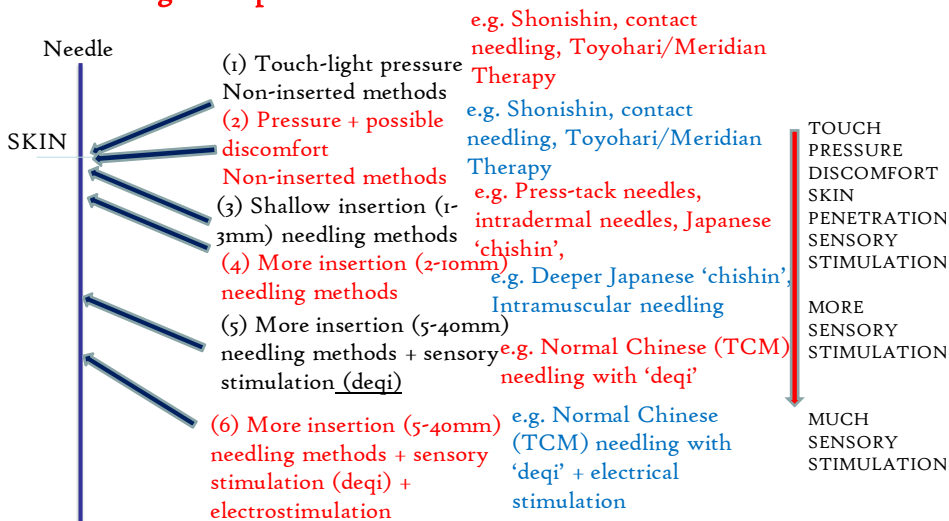
When we apply acupuncture by inserting needles with deqi, adding specific electro-stumm to the needles, what mechanisms are triggered?

Few if any studies have investigated

What mechanisms are triggered when we apply acupuncture treatment? (ie the whole treatment based on the diagnosis)

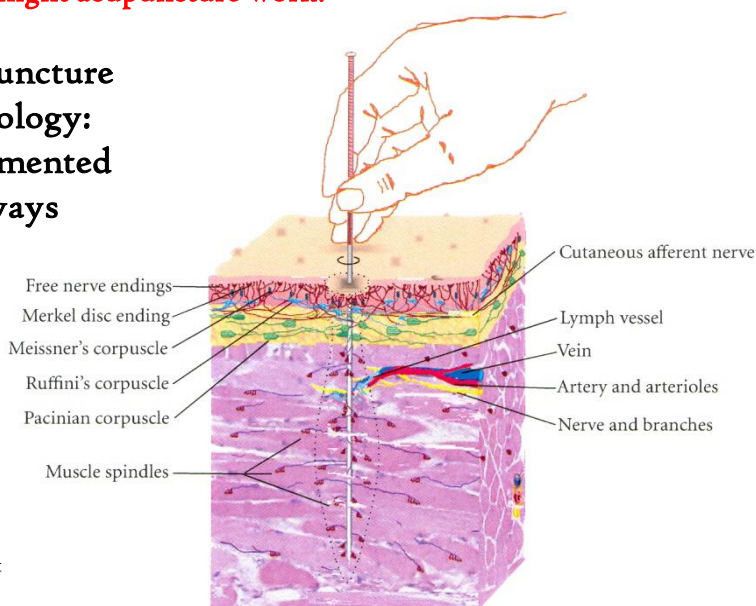
What mechanisms are triggered by simple insertion of a needle?

How might acupuncture work?



How might acupuncture work?

Acupuncture physiology: Documented pathways



From
Zhang et
al. 2012

How might acupuncture work?

Range of measured physiological effects of soft touch / pressure

Effects of soft touch, soft pressure & soft stroking	Epithelial cells/macrophage – glutamate/aspartate
	Epithelial cells, T cells, macrophages – calcitonin gene related peptide
	Mast cells, fibroblasts, platelets, keratinocytes, macrophages – Substance P
	Keratinocytes, melanocytes, dermal fibroblasts, leucocytes – β-endorphin
	Epidermal cells – ATP/cGMP
	Mast cells – histamine
	Platelets, mast cells – serotonin
	Nitric oxide
	[Zhang 2012]
	- Unmyelinated C tactile fibers [Chae, Olausson 2017]
	- Polymodal neurone receptor [Kawakita et al. 2006]
	- Peripheral microcirculatory effects [Ogawa-Ochiai et al 2020]
	- Cardiovascular responses leading to reduced cardiac workload [O'Brien et al. 2013]

How might acupuncture work?

There are a number of documented and thus predictable responses to **touch** involving two afferent nerve fibres.

The first are myelinated A β fibres which are involved in providing discriminative spatial information and can trigger rapid responses (such as the fight or flight response) [Chae, Olausson 2017].

The second are the unmyelinated C tactile fibres which are activated with low velocity dynamic touch “mostly involved in affective and motivational functions and plays an important role in many forms of social communication” [Chae, Olausson 2017] releasing oxytocin to help produce these effects [Walker et al. 2017].

The role of touch in acupuncture treatment

Acup Med 2017

Younbyoung Chae,¹ Håkan Olausson²

Neuropeptides 69 (2017) 27–38



Contents lists available at ScienceDirect

Neuropeptides

Journal homepage: www.elsevier.com/locate/nepep

News and reviews

C-tactile afferents: Cutaneous mediators of oxytocin release during affiliative tactile interactions?

Susannah C. Walker^{1,2}, Paula D. Trotter³, William T. Swaney⁴, Andrew Marshall^{4,5}, Fran

nature
neuroscience

Coding of pleasant touch by unmyelinated afferents in humans

Line S Löken^{1,2}, Johan Wessberg¹, India Morrison^{1,2}, Francis McGlone^{3,4} & Håkan Olausson^{1,2}

How might acupuncture work?

Soft stroking has also been found to modulate pain in infants [Gursul et al. 2018]

and adults [Habig et al. 2017, Liljencrantz et al. 2017]



Current Biology Magazine

Habig et al. BMC Neurology (2017) 17:184
DOI: 10.1186/s12875-017-0463-6

BMC Neurology

Correspondence Stroking modulates noxious-evoked brain activity in human infants

Denis Gursul¹, Sevgi Güneş¹, Candice Hertling¹, Gabriele Schenck-Mellado¹, Fiona Moutlin¹, Amy Honzik¹, Elise Adams¹, Gareth Hathway¹, Susannah Walker¹, Francis McGlone^{1,2}, and Rebecca Slater^{1*}

reduced noxious-evoked responses in a clinical context in an independent sample of infants (Study 2). In Study 1, CT-optimal touch significantly reduced noxious-evoked brain activity following the first acute experimental noxious stimulus ($p = 0.009$). Linear mixed effects analysis (Figure 1B). In contrast, CT non-optimal touch did not significantly reduce noxious-evoked brain activity ($p = 0.257$, linear mixed effects analysis; Figure 1B), demonstrating the specificity of the response to lower velocity stroking. In the CT-optimal condition, the attenuation of noxious-evoked brain activity was not maintained across repeated stimuli ($p = 0.04$, 10^4 permutations).

RESEARCH ARTICLE Open Access

Low threshold unmyelinated mechanoreceptors can modulate pain

Kathrin Habig¹, Anne Schänzer², Wolfgang Schirner³, Gotthye Lautenschläger¹, Benjamin Dasinger⁴, Hilan Claussner⁴, Frank Bräken⁵, Elke R. Gzewiek⁶ and Heidrun H. Krämer¹

Touch can also trigger protective actions (fight or flight) responses and complex bio-psycho-social responses [Leder, Krucoff 2008] that can result in part depending on the initial condition of the person touched and in part how the touch is perceived.

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 14, Number 3, 2008, pp. 321-327
© Mary Ann Liebert, Inc.
DOI: 10.1089/jam.2007.07.17

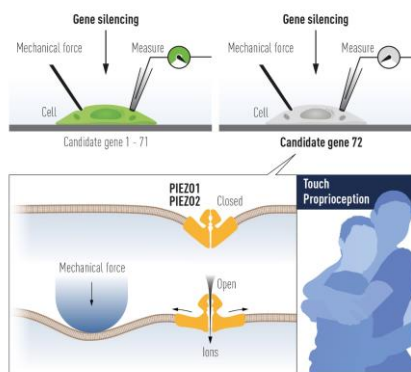
PARADIGMS

The Touch That Heals: The Uses and Meanings of Touch in the Clinical Encounter

How might acupuncture work?

Touch also plays an important role in helping identify and learn boundaries which has played essential functions in growth and development on both evolutionary and individual scales

One of the 2021 Nobel prizes in biology was awarded because of work done identifying mechanical touch mechanism receptors (Piezo 2) seen as important in proprioception
Nobel Prize 2021
(Ardem Patapoutian)



How might acupuncture work?

In addition to the above mechanisms that can be triggered by softer touch additional mechanisms may also be triggered

- Increase peripheral microcirculation [Ogawa-Ochiai et al. 2020]
- Potential healing and reparative effects as well as effects on some medical problems [Sparber et al. 2003, Warber et al. 2003]
- Psycho-physiological effects of touch including: stress reduction, pain reduction, growth and development effects, immune function effects, and auto-immune disorder effects [Field 2000]

How might acupuncture work?

INCREASED PRESSURE
of Touch & stroking (non-noxious)

How might acupuncture work?

Documented additional effects of **increased pressure**

Myelinated A β fibres - **involved in providing discriminative spatial information and can trigger rapid responses** - such as the fight or flight response [Chae, Olausen 2017]

- Parasympathetic mediated effects [Chen et al. 2013]
- Various cell types can be involved including **Merkel cells** to trigger pathways involving Somatostatin and Noradrenalin, **Keratinocytes** to trigger Somatostatin mediated effects and **macrophages, lymphocytes** to trigger γ -aminobutyric acid (GABA) related effects [Zhang et al. 2012]

How might acupuncture work?

If the body perceives any treatment effects to be biologically NOXIOUS (uncomfortable, discomfort, pain)

How might acupuncture work?

Documented additional effects of nociception

- Pain modulation - via

- homo-segmental mechanisms [Gomes, Leao 2020],
- hetero-segmental mechanisms [LeBars et al. 1989]

stimulation of

- unmyelinated C tactile fibers [Chae, Olausson 2017]
- polymodal neurone receptors [Kawakita et al. 2006].
- & potentially:
- Skin/muscle pain receptors transmit signals triggering release of enkephalin or dynorphin in the spinal cord,
- enkephalin in the midbrain periaqueductal grey region,
- β -endorphin from pituitary-hypothalamic complex

BUT these usually require heavy stimulation to produce predictable release

- [Pomeranz, Berman 2003] On the mechanisms of physiological activities produced by various sham interventions used in recent clinical trials of acupuncture

Kenji Kawakita, Maria Carneiro and Kaoru Okada

How might acupuncture work?

Inserted needling – without much sensation & with deliberately provoked strong stimulation (deqi)

How might acupuncture work?

Additional effects of **needle insertion**

Current of injury - **triggering protective, reparative and healing effects** [Oschman 2000]

Systemic microcirculatory effects [Itaya et al. 1987, Huang et al. 2012]

Cardiovascular effects [O'Brien et al. 2013]

ANS mediated effects [Lee, Ernst 1988, Li et al. 2013, Nishijo et al. 1997, Tanaka et al. 1997]

Effects on the brain:

Default mode network by increasing functional connectivity [Dhond et al. 2008, Lin et al. 2016, Zhang et al. 2019]

Somatosensory, affective and cognitive processing [Zhang et al. 2019]

Sensorimotor Network, Salience Network and the Descending Pain Modulatory System [Yu et al. 2020]

How might acupuncture work?

Influences on regions of the brain: insula, thalamus, anterior cingulate cortex, medial prefrontal cortex, posterior cingulate cortex, amygdala, limbic-paralimbic neocortical network [Chae et al. 2013, Zhang et al. 2019, Huang et al. 2012]

Additional measured effects

Anti-inflammatory effects [McDonald et al. 2013, Zijlstra et al. 2003]

Immunological effects [Mori et al. 2002, Aguiar et al. 2012, Yamaguchi et al. 2007]

INCREASED RELAXATION & CALMING

Different acupuncture needling techniques can produce increased states of relaxation [Cabioglu et al. 2012, Guimaraes et al. 1997, Hollifield et al. 2007, Huang et al. 2011, Lee et al. 2019, Pavao et al. 2010, Schroeder et al. 2017, Wild et al. 2020], some forms of needling more than others,

In some treatment systems and with some patients....treatment is done to CREATE increased relaxation

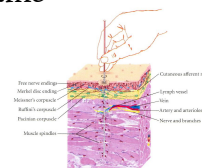
How might acupuncture work?

Therefore needling techniques may also produce the accompanying physiological effects of the relaxation response

“reductions in volumetric oxygen consumption (VO₂), carbon dioxide elimination, a slowing of the heart and respiration rates, a drop in systolic and diastolic blood pressure, and an increase in heart rate variability” [Dusek, Benson 2009]

Needling can act through multiple pathways at the same time

Different techniques will work through different pathways, with an overlap



Needling deeper to stimulate structures and mechanisms will necessarily also stimulate surface structures and mechanisms

Clinical trial design overview

In a clinical trial patients are randomly assigned to one of two or more treatment groups

Patients are assessed using the outcome measure before treatment begins

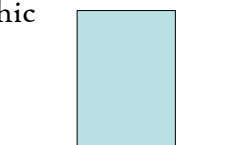
Patients are then assessed with the same outcome at different points after treatment begins

e.g. at end of treatment

Halfway through treatment and at end of treatment

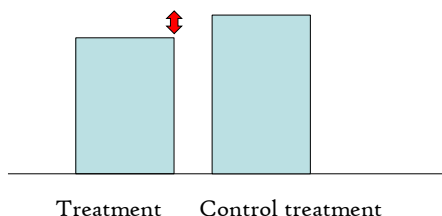
And often at 3 &/or 6 &/or 12 months after treatment end

Example of outcome measure graphic



Clinical trial design overview

Since patients are assigned to e.g. 2 groups the outcome graphic shows the comparison



Statistical testing is done on the **difference** between the two measures

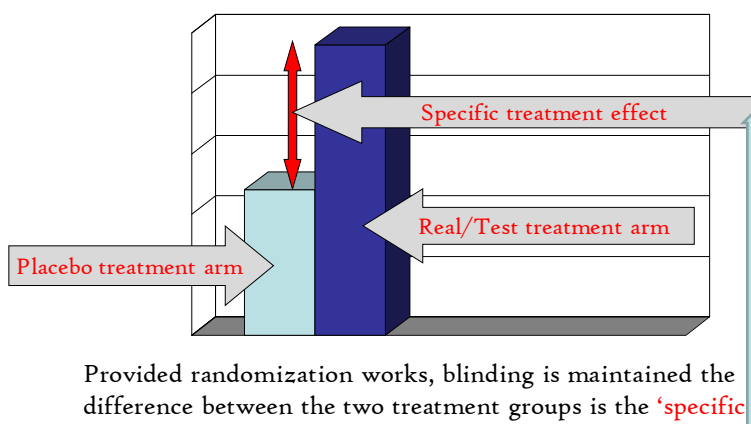
Before treatment begins the difference should be small and NOT statistically significant ($p > 0.05$)

After treatment start if the difference starts to become statistically significant ($p < 0.05$) it indicates one treatment is more effective than the other

Clinical trial design overview

Once treatment begins the outcomes start to be different

Comparison of placebo and real/test treatment arms



Provided randomization works, blinding is maintained the difference between the two treatment groups is the '**specific treatment effect**'

Statistical testing focus on determining the size of this difference. Effect sizes are based on this calculation

Clinical trial design overview

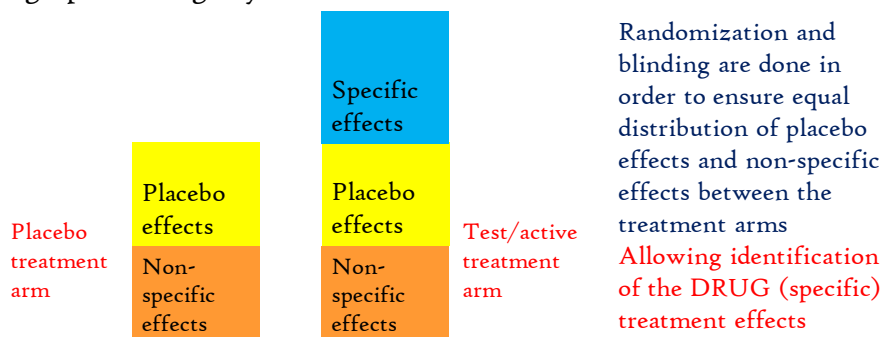
BUT change in the outcome occurs not only because of the type of treatment given and any placebo effects, but also due to other things like the passage of time e.g.

Regression to the mean

Chance

These are often called ‘non-specific effects’

So when comparing test treatment to placebo treatment the graphic is slightly different.....



Clinical trial design overview

But in acupuncture trials there are several important issues that come up:

1- Sham physiology

The control treatment is NEVER inert

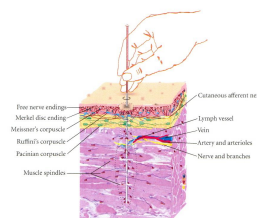
Whatever treatment technique is applied

ALWAYS involves touch, usually pressure

Usually insertion and often with some

nociception

As the needle is placed deeper, more and more structures and mechanisms can be triggered



IF the intention is to use a technique for the sham

acupuncture that **avoids the sensory stimulation (deqi)** by

simply inserting needles shallowly (started 1980s) it is

IMPOSSIBLE to avoid mechanisms associated with touch, pressure, skin insertion, possibly nociception

Clinical trial design overview

If the intention is to use a technique for the sham acupuncture that avoids skin insertion (started 1998) it is IMPOSSIBLE to avoid mechanisms associated with touch, pressure, possibly nociception

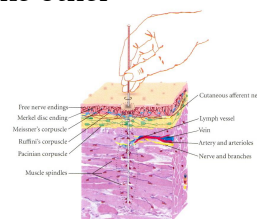


As we saw yesterday, acupuncture is VERY diverse Including techniques applied gently or with more pressure to the skin surface only, needles shallowly inserted and without sensation, more deeply inserted with increasing sensation etc.

Lack of knowledge of the nature of acupuncture practice led researchers to try using either shallow insertion needling (minimal needling) [Vincent 1989] or non-inserted needling [Streitberger et al. 1998, Park et al. 2000, Takakura et al. 2007] as the sham tx

Clinical trial design overview

THEREFORE in addition to the general non-specific effects
In addition to any placebo effects
The sham acupuncture ALWAYS triggers some other physiological effects
Some of which are part of how acupuncture might work



Despite warnings about this problem in a landmark paper in 1983 [Lewith, Machin 1983] and in many papers since then
Researchers continue to NOT KNOW this, pretend it is not important or simply dismiss it as the biased complaints of practitioners [Kaptchuk 2020]

Clinical trial design overview

In a new study on sham acupuncture, we found 51 RCTs that measured biomarkers in both the test and sham treatment groups



SYSTEMATIC REVIEW
published: 10 February 2022
doi: 10.3389/fnins.2022.834112



We found for example that Non-penetrating sham techniques can influence a range of Biomarkers:

Plausible Mechanism of Sham Acupuncture Based on Biomarkers: A Systematic Review of Randomized Controlled Trials

Tae-Hun Kim¹, Myeong Soo Lee^{2*}, Stephen Birch³ and Terje Alraek^{4*}

Inflammation & immune modulatory biomarkers

serum TNF- α + CRP, IFN- γ , IL-1, IL-10, IL-12, IL-6, TNF- β

Metabolic biomarkers

Cortisol, Ghrelin, HbA_{1c}, HDL, LDL, Leptin, TC, TG

Neuroregulatory biomarkers

Serum adrenaline, β -endorphin, noradrenaline

Clinical trial design overview

The implications and effects of including unknown physiological effects in the control treatment arm are profound:

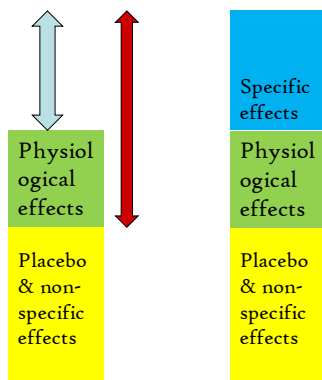
- a) Need HUGE numbers of patient to demonstrate statistically significant differences and avoid type II errors (false negative conclusions) [Lewith, Machin 1983]
Money for research is always hard to get and even more so for acupuncture....thus almost all acupuncture studies with a sham control treatment do NOT have enough patients to avoid type II errors (false negative errors)
- b) The additional physiological effects of the sham beyond placebo and non-specific effects usually makes the measured outcome larger in the control treatment arm

What happens when the sham treatment is NOT INERT?

Researchers think they are testing this difference

But the testing of this difference is always smaller.... creates Underestimation

Meaning it becomes routinely more difficult to find statistically significant differences between the treatments



Use of sham acupuncture as a control treatment has been shown to routinely underestimate the effectiveness of acupuncture [MacPherson et al. 2017]

This creates bias against acupuncture [Appleyard et al. 2014] Especially because these additional physiological effects are part of how acupuncture works [De Craen et al. 1990, Birch 2006]

Clinical trial design overview

These findings lead to other important conclusions

We have seen that there is a steadily growing number of reviews that have found acupuncture to be more effective than sham acupuncture.

Since sham acupuncture trials underestimate the effectiveness of acupuncture this means

When sham acupuncture trials are included in systematic reviews or meta-analyses, acupuncture is **more effective than the analyses (statistical tests) show**, but by an unknown amount

At present as this is gradually becoming recognised, there are still no acceptable ways for researchers to adjust their tests and results to account for this

While researchers are confused clinicians are increasingly not – evidenced by the number of recommendations to use acupuncture

Clinical trial design overview

But in acupuncture trials there are several important issues that come up:

2- Sham treatment selection

A core idea for all styles of acupuncture is that after evaluating the patient, we needle certain acupoints with certain techniques

While there are many different variables that go into an acupuncture treatment there are two key variables

Location of needling
Technique of needling

Ultimately whatever diagnostic approach one uses, the result is to choose certain points to be treated with certain techniques

Clinical trials have focused almost exclusively on testing these

Clinical trial design overview

Real + Sham Acupuncture

	Real	Sham
Selected Points	RP	SP
Needling Techniques	RT	ST
	↑	↑
'real acupuncture' =	RP + RT	
'sham acupuncture' =		SP + ST

With two major variables there are therefore 3 possible sham variations, each answering very different questions

Clinical trial design overview

Sham variations



ST at RP = Comparison/test of technique effects only (1)

RT at SP = Comparison/test of point location effects only (2)

ST at SP = comparison 'real' acupuncture to possible placebo

Clinical trial design overview

ONLY the application of ST at SP can act as a control treatment that could possibly control for placebo effects

When you apply the real (RT) and sham (ST) techniques to the same acupoints, provided randomization and blinding are used, placebo is HELD EQUAL between groups, the two needling techniques are compared to each other. IMPOSSIBLE to control for placebo in the sense of comparing acupuncture to placebo

Likewise when you apply the same needling technique to the real points (RP) and the sham points (SP), you hold placebo equal and can only compare the effects of different points to each other

Neither of these models are tests of the effectiveness of acupuncture

Clinical trial design overview

Why is this important?

Because DOZENS of research groups screwed up on this

They applied both the real and sham techniques to the same points while thinking they had tested acupuncture in a placebo controlled trial

A 2009 study by So et al in Hong Kong found that the sham (non-penetrating needle) treatment was **significantly more effective** than the 'real' acupuncture for IVF [So et al. 2009]

A 2015 systematic review identified a little over 30 trials that made this mistake [Zhang et al. 2015] & that these sham techniques are significantly effective treatments



RESEARCH ARTICLE

Placebo Devices as Effective Control Methods in Acupuncture Clinical Trials: A Systematic Review

Claire Shuiqing Zhang¹, Hsiewe Ying Tan¹, George Shengxi Zhang¹, Anthony Lin Zhang¹, Charlie Changli Xue¹, Yi Min Xie^{2*}

Clinical trial design overview

Why is this important?

We have found 80 trials so far that have made this mistake [Birch et al. in preparation]

Among those we found:

Several of the groups that developed the non-penetrating sham devices (including Streitberger, Takakura) also mistakenly used the wrong sham design (that compares needling techniques to each other)

and themselves have demonstrated that their sham treatment devices are inappropriate for use in clinical trials of acupuncture [Kleinhenz et al. 1999, Streitberger et al. 2003, Takakura, Yashima 2009, Goldman et al. 2008, Vase et al. 2013]

This includes Kaptchuk's Harvard based placebo group!

Clinical trial design overview

Why is this important?

This shows that even the so-called experts do not know what they are doing and have made significant errors in their work

This has knock on effects across how we understand and interpret clinical trial; results where acupuncture was compared to some form of 'sham' acupuncture

This is most obvious when we examine the notion of 'placebo'

Of Note.....problems in research in medicine are not limited to acupuncture they are found across all areas of research

In the 1990s estimates found that only around 2% of studies in medicine were of sufficient quality... A recent estimate shows that this number has risen to 6%!



Journal of Clinical Epidemiology 148 (2022) 160–169

Journal of
Clinical
Epidemiology

ORIGINAL ARTICLE

Most healthcare interventions tested in Cochrane Reviews are not effective according to high quality evidence: a systematic review and meta-analysis

Jeremy Howick^{a,b,c,*}, Despina Koletsis^{c,d}, John P.A. Ioannidis^d, Claire Madigan^e, Nikolaos Pantis^f, Martin Loeff^g, Harald Walach^h, Sebastian Sauer^h, Jos Kleijnen^b

Clinical trial design overview

3- Sham and confusion with placebo

Sham controlled trials of a therapy are done in order to control for placebo effects

In a trial of a drug, the drug can be compared to its placebo

The placebo should look like the drug so that neither patient nor practitioner know which is given (double blinding) & the placebo pill is INERT

For a medical technique or device efforts are made to make something that looks/feels the same and is INERT, this is called a 'sham' treatment

To control for placebo in a trial the control treatment

Must be indistinguishable from the test treatment

Blinding must be ensured to guarantee this

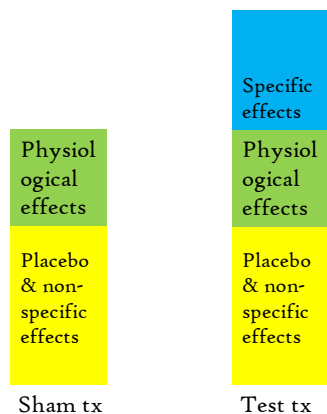
Randomization must be used

The control treatment must have none of the active components of the test treatment and is ideally 'inert'

Clinical trial design overview

3- Sham and confusion with placebo

As we have seen, none of the sham techniques are inert



Since many researchers do not know, ignore or dismiss this, it is common to describe the sham treatment as a 'placebo'

It cannot be a placebo, placebo is part of the yellow area, it cannot include the green area

If the trial or review finds that the test acupuncture is NOT statistically more significant than the sham then they say acupuncture is not more effective than placebo & **ACUPUNCTURE IS PLACEBO**

Clinical trial design overview

3- Sham and confusion with placebo

How common is this mistake (assuming that sham=placebo)?

In a mid 1990s review 12/17 (71%) sham studies (1974-96) said sham=placebo [Birch 1997]

24 of 30 studies (80%) (1999-2014) included in review of sham techniques said sham=placebo [Zhang et al 2015]

58 of 80 studies (58%) (1999-2016) included in review of sham techniques said sham=placebo [Birch et al in preparation]

In the latter two...all studies were sham-3 trials where placebo is held equal between treatment groups....acupuncture is NOT compared to placebo

Clinical trial design overview

3- Sham and confusion with placebo

In an ongoing study of Cochrane reviews that discuss sham acupuncture, we have found between 60% and 72% of the reviews describe sham acupuncture as placebo [Birch et al. in preparation]

When researchers state that sham=placebo it can significantly mislead readers and consumers of the research

This is a big problem when the world's leading review group (Cochrane Collaboration) does this

In addition to this confusion of labelling what are the other implications?

To date no clinical trials have successfully controlled for placebo

It is NOT POSSIBLE to make a statement about the size and role of placebo in acupuncture

Clinical trial design overview

Pragmatic trials

Pragmatic trials are efforts to test a treatment in more real-world settings, where the treatment is not constrained by the requirements of the placebo controlled (explanatory) trial

There are several types of pragmatic trial:

A- Patients receive either the test treatment or no additional treatment

Acupuncture vs no treatment

B- Patients receive either the test treatment or the usual treatment

Acupuncture versus standard care (drug/physio, etc.)

C- Patients receive either the test treatment with the usual treatment or only the usual treatment

Acupuncture and rehab vs rehab alone

Clinical trial design overview

Pragmatic trials

Each tests and examines a different question

In A- acupuncture versus no treatment

This examines if acupuncture contributes to an improved condition beyond simply the passage of time

It is useful to examine if acupuncture could play a role in health care for that patient population

Public health studies might also use this

In B- acupuncture versus standard care

This examines if acupuncture is at least as good as if not better than the treatment that is usually given

This can be helpful when the usual treatment has a lot of adverse effects or is not tolerated or rejected by some patients

Clinical trial design overview

Pragmatic trials

In C- standard care + acupuncture versus standard care alone

This is useful when patients must do a particular treatment for their problem and we want to see if acupuncture improves the effects

This can occur by adding new treatment effects, enhancing the effects of the usual treatment or addressing unwanted side effects that make it likely for the patient to stop the usual treatment

All of these models can be used to explore cost-effectiveness, adverse effects of acupuncture and so on

None of these models are able to address questions about the role of placebo

As we have seen, in medicine it is important for the credibility of a therapy to have been through the fire of placebo testing

Clinical trial design overview

FUTURE TRIALS

If sham acupuncture studies are not possible or only lead to results that are confusing to interpret and understand

&

Pragmatic trials are not capable of addressing the issue of placebo....how to proceed?

Fortunately DESPITE the problems of sham acupuncture (which underestimates the effects of treatment) acupuncture has been found more effective than sham in many studies

The placebo issue is kind of dealt with already.....

THUS it is better to do the following:

Test acupuncture in pragmatic trials and at the same time conduct parallel laboratory studies to explore the mechanisms of action [Hyland 2003]

Systematic reviews and meta-analyses

These are the methods and tools used to systematically search for, analyse and present evidence for something so that it is easier to make an assessment of whether that thing is useful, effective and so on

Systematic reviews – have become more common and allow a broader analysis of the overall data

Meta-analysis – are now relatively less common as they require that the same outcomes be used in the included studies to permit the specialized statistical testing

Clinical Practice Guideline – goes beyond the systematic review and meta-analysis as instead of focussing on the question does a therapy work, it attempts to answer the questions which therapies are helpful? How to prioritise therapies in terms of effectiveness & safety & cost-effectiveness to give more specific guidance to health care workers

Systematic reviews and meta-analyses

The Systematic Review (SR) became more common in the 1990s especially after the international evidence based medicine group 'Cochrane Collaboration' was formed

Cochrane Reviews are considered the highest quality and most trustworthy (see: <https://www.cochranelibrary.com/>)

SRs are commonly used to examine treatment of a particular health problem X

They are commonly used to examine a single therapy for X but are also commonly used to examine all therapies for X

They should systematically search all available databases for any studies that test a therapy for X – developing a search strategy is important and requires access to multiple databases

All studies that are found are then screened following set criteria that are established before the search begins

Systematic reviews and meta-analyses

The screening process using these criteria is used to eliminate publications from further consideration, examples of selection criteria:

the study must have used the correct methods for identifying patients with X

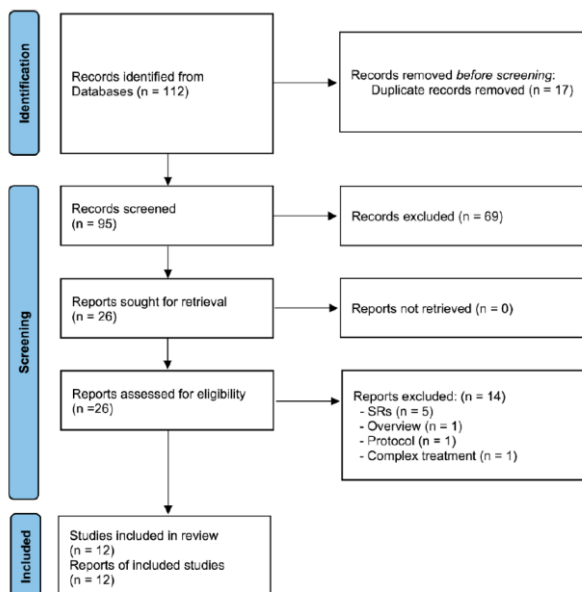
The study must have applied a randomization method

The study must have used acupuncture needles (not moxa or acupressure).....and so on

Eventually a much smaller number of studies remain which are then included in the analysis

Systematic reviews and meta-analyses

Example of how the search results are presented



From Choi et al. 2022

Figure 1. Flow chart of study selection. AT: acupuncture; SRs: systematic reviews.

Systematic reviews and meta-analyses

Example of study data presentation

Author (Year) [Ref]	Sample Size/ Cancer Stage/ Country	Intervention (Regimen, Randoimized/ Analyzed)	Control (Regimen, Randoimized/ Analyzed)	Fatigue Measurement	Result	AEs/Trial Registration Number
Li (2020) [34]	40/I to III/ongoing-chemo A: 47.5; B: 42; C: 50.5 n = 20/18	(A) AT (1 time weekly for 20 weeks,	(B) Sham AT (noninsertive stimulation at non-AT points, n = 10/10) (C) UC (n = 10/10)	MFI-20	A vs. B: MD -5.90 [-17.43, 5.63], p = 0.32; A vs. C: MD -13.70 [-28.50, 1.10], p = 0.07	Bruising ChiCTR-IPR-17013652
Smith (2013) [35]	30/NR/off-treatment A: 55.0; B: 53.0; C: 58.0	(A) AT (2 times weekly for 3 weeks and once weekly for 3 weeks, n = 10/9)	(B) Sham AT (noninsertive stimulation at non-AT points, n = 10/10) (C) WLC (n = 10/10)	BFI	A vs. B: MD -1.70 [-3.70, 0.30], p = 0.10; A vs. C: MD -2.20 [-4.16, -0.24], p = 0.03	NR/ACTRN12610000720011
Mao (2014) [36]	67/I to III/ongoing-HT A: 57.5; B: 60.9; C: 60.6	(A) EA (2 times weekly for 2 weeks and once weekly for 6 weeks, n = 22/21)	(B) Sham EA (noninsertive stimulation at non-AT points, n = 22/20) (C) WLC (n = 23/22)	BFI	A vs. B: MD -0.80 [-2.40, 0.80], p = 0.33; F/U: MD -0.70 [-2.13, 0.73], p = 0.34 A vs. C: MD -1.90 [-3.32, -0.48], p = 0.008; F/U: MD -1.60 [-3.14, -0.06], p = 0.04	NR/NCT01013337

AEs: adverse events; AT: Acupuncture; BFI: Brief Fatigue Inventory; Chemo: Chemotherapy; ER: Effective rate; F/U: Follow-Up; HT: Hormonal therapy; MFI: Multidimensional Fatigue Inventory; NR: Not Reported; PFS: Piper fatigue scale; RR: Risk Ratio; RT: radiotherapy; MD: Mean Difference; UC: Usual Care; WLC: Wait List Control.

From Choi et al. 2022

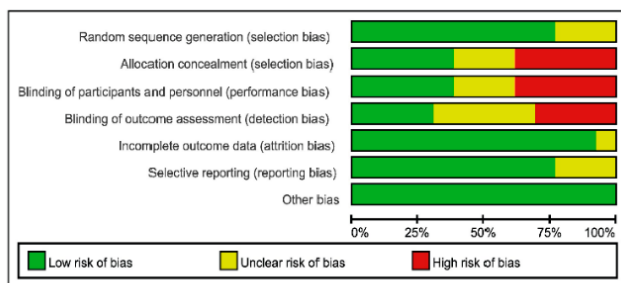
Systematic reviews and meta-analyses

Each study is then evaluated for bias using the 'Risk of Bias' tool - a series of questions asked about the study that attempt to evaluate whether the study was at risk of certain problems that might bias in favour of a positive result

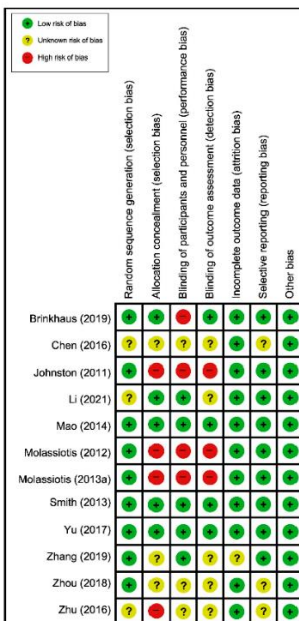
Studies are rated as **low**, **unclear** or **High** risk of bias

From Choi et al. 2022

(A) Risk of bias graph



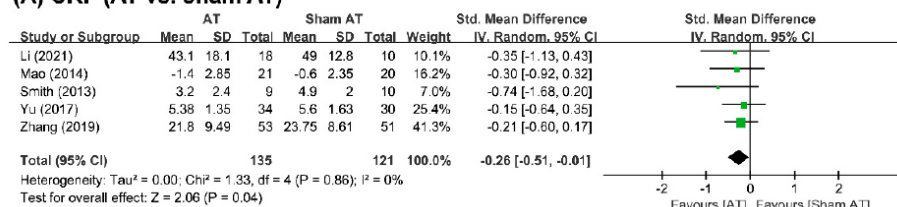
(B) Risk of bias summary



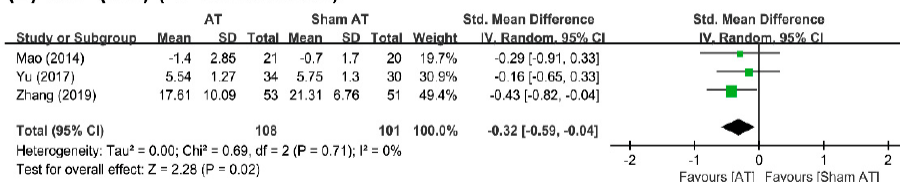
Systematic reviews and meta-analyses

Examples of data presentation for the included studies

(A) CRF (AT vs. sham AT)



(B) CRF (F/U) (AT vs. sham AT)



From Choi et al. 2022

Systematic reviews and meta-analyses

Meta-analyses use the same methods for searching, screening, presenting data from studies process

BUT

Because in the included studies where the meta-analysis can be done the same outcome was used, this permits pooling all data from the included studies into a single more precise type of statistical testing

It is quite common that reviewers perform a systematic review, and when they find enough studies that have used the same critical outcome, they can add the more precise analysis of the meta-analysis



Systematic Review

Acupuncture for Managing Cancer-Related Fatigue in Breast Cancer Patients: A Systematic Review and Meta-Analysis

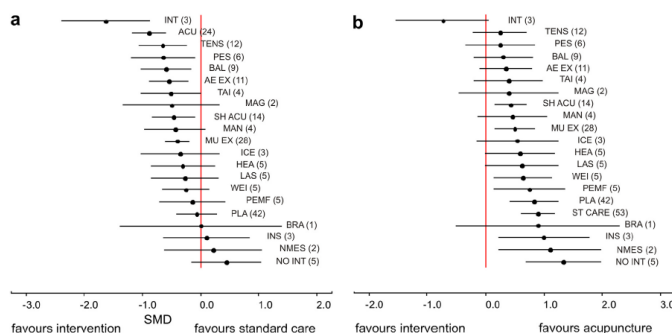
Tae-Young Choi ¹, Lin Ang ¹, Ji Hee Jun ¹, Terje Alraek ^{2,3}, Stephen Birch ², Weidong Lu ⁴ and Myeong Soo Lee ^{1,*}

Systematic reviews and meta-analyses

Certain forms of meta-analytic testing permit more comparisons of the results for different interventions to each other and rate the relative strength of evidence for therapies against each other

The network meta-analysis has certain requirements within the treatment arms and methods for the included studies in order to be able to proceed

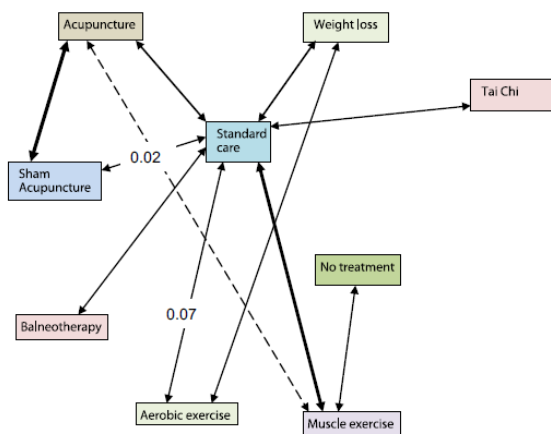
Example of results presentation



From Corbett et al. 2013

Systematic reviews and meta-analyses

Example of presentation of results

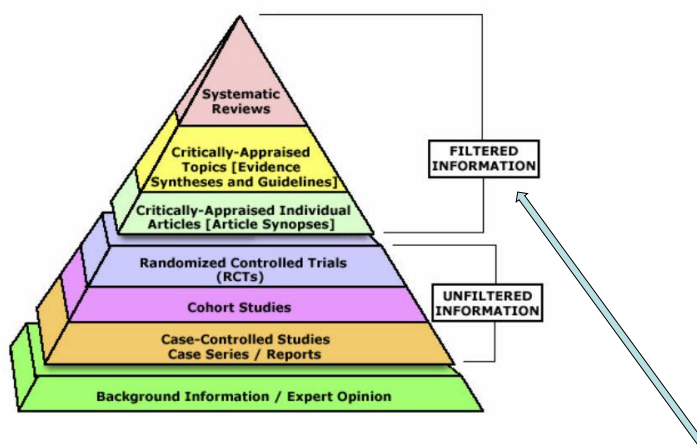


From Corbett
et al. 2013

Fig. 2. Network diagram for the end of treatment analysis of better-quality trials. The number of trials and patients included in the analysis are stated in Tables II(c-d). Each solid arrow indicates that there is a data point for that comparison entered into the analysis. The thickness reflects the number of trials. The dotted line reflects an extra comparison in a multi-arm trial. The numbers are a measure of inconsistency: 0 is no inconsistency; 1 is complete inconsistency.

Systematic reviews and meta-analyses

In medical research reviews have long been considered the top of the evidence pyramid



There are clear rules and guidelines for how reviews can and should be done with evaluation to try to ensure the highest quality

Systematic reviews and meta-analyses

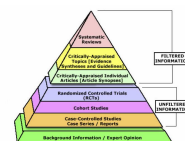
For acupuncture though, it is not clear whether the existing systems are enough



We have seen that since sham acupuncture is NEVER INERT and that the mechanisms sham techniques can trigger are part of how acupuncture will work
This creates the situation where sham studies routinely underestimate the effectiveness of acupuncture and
Where sham studies bias against acupuncture
The Risk of Bias (RoB) tool rates a study that does not use sham acup as at high risk of bias
But if the researchers deliberately avoid using sham because of its problems they are being penalised for the evidence based approach they choose and not rewarded for it
The RoB needs to be modified to deal with this [Appleyard et al. 2014]

Systematic reviews and meta-analyses

We have also see that acupuncture is a difficult thing to investigate not least because most researchers do not have enough information about it and tend to make faulty assumptions about it [Birch et al. 2021, 2022]



A key assumption is that sham acupuncture IS a placebo treatment

We have seen it cannot act like that

We have seen between 61-72% of Cochrane reviews that have discussed sham acupuncture have made statements that sham acupuncture IS a placebo [Birch et al. in preparation]

When the highest level of Evidence Based Medicine publication make these kinds of statements it strongly influences readers and consumers

Medical experts, Government regulators and so on

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

How much of what is taught at an acupuncture school based on TEAM theories has been scientifically tested? How much validated?

How much of what a practitioner of TEAM based acupuncture practices has been tested? How much validated?

We are all aware that acupuncture is not a routinely accepted therapy. It tends to lie outside mainstream healthcare systems, even for those doctors, nurses and physiotherapists that practice it

The situation is even more intense for those of us that practice TEAM based acupuncture since our concepts, theories, diagnoses and general descriptions are also quite foreign

Over time more and more doctors, nurses, physios practice acupuncture based on modern medical ideas

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

If we do not start figuring out how to test and validate what we teach and practice as TEAM based acupuncture practitioners, eventually we will be replaced, eliminated

To date we have managed (not very well)...so we are tolerated....we are still here.....

But if we do not develop the evidence to support what we do, it will be replaced by simple procedures

My teachers in Japan have been worrying about this for decades and I have been working gradually towards this for decades

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

What evidence do we have for the conceptual basis of what we do (meridians, acupoints, qi, yin-yang etc)?

ALMOST NOTHING - I will go over this briefly a bit later

What evidence do we have for the diagnostic methods we use?

VERY LITTLE

What evidence do we have for the diagnostic patterns we use?

VERY LITTLE

What evidence do we have that using treatment based on the TEAM diagnoses is more effective than not doing that, or even relevant?

ALMOST NOTHING

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

What is the evidence for the diagnostic methods we use?

Pulse diagnosis, Tongue diagnosis, visual inspection, other observations - almost nothing [O'Brien, Birch 2009]

How to develop evidence for the diagnostic methods we use?

Medicine follows the scientific method as best it can to reduce the risk of mistakes (e.g. mistaken judgements in diagnosis) and to ensure that we are all talking about the same thing

The tendency in modern medicine is to limit naked sense observations and use clinical tests, measurements as much as possible

ANY observation ANY clinical measurement or test

MUST be validated to ensure accuracy and consistency

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

A key aspect of this validation is that practitioners trained in the same methods make the same observations

It is vital that what is observed is both stable/consistent AND that others can agree on observing that thing

There are specific forms of testing to test and confirm the consistency of the observations:

Intra-rater reliability – where a person under controlled conditions records their observations of the same thing several times within a certain time frame

the results are tested for consistency of the observations

Inter-rater reliability – where a number of people record their observations of the same thing separately from each other

the results are tested for consistency between people

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

Intra- and inter-rater reliability testing is used not only for a person using naked sense observations, it is also used whenever a matching measures something

It is a fundamental step in any validation

Take e.g. tongue diagnosis

Study type 1

X number (e.g. twenty) people sit behind screens in such a way that only their tongue is exposed with a consistent light source

A practitioner examines each tongue at least 3 times in random sequence and records their observations

Each tongue should have the same observations recorded

How to record the observations needs to be standardised and set up in such a way as to allow the statistical testing to be performed

The practitioner should not have access to any other data about the patient so they cannot tell one from another, etc.

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

Study type 2

X number (twenty) people are examined by 2 or more (ideally at least 3) practitioners can record tongue observations on a standardised form

The similarly trained practitioners are isolated from each other and only one practitioner at a time makes the observation

There should be agreement between practitioners on what is recorded

It is necessary to ensure that what is recorded is accessible to the selected statistical testing methods

These types of study are easy to do, can be used for any kind of data gathering (4 diagnoses) and do not cost much

It is vital that a qualified statistician is involved to ensure that the correct statistical tests are used, the forms are designed to permit use of those tests and enough patients are examined

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

Discussions with a TCM professor in Seattle in the early 1990s revealed that in China they had attempted these studies with senior practitioners for tongue and pulse diagnosis

The results were AWFUL

It was decided to build technological tools for making and rating tongue observations, pulse observations and to try to 'objectify' results this way

NICE IDEA....but....

Since practitioners could not agree on what is e.g. wiry pulse or specific tongue coating then there is NO EVIDENCE to support the machine settings that rate 'wiry pulse' or 'this coating'

Thus the attempts failed

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

What evidence do we have for the diagnostic patterns we use?

In TEAM based practice systems diagnostic conclusions are drawn as ‘patterns...

Bian-zheng – pattern identification [Birch, Alraek 2014, Birch et al. 2020]

With the many systems of TEAM practice there are many different descriptions of ‘patterns identification’

How much evidence is there for pattern identification? **Very little** [O’Brien, Birch 2009]

How much for TCM pattern identification? **Very little** [Popplewell et al. 2018, Jacobson et al. 2018]

How to develop the evidence for the diagnostic patterns?

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

The international Pattern Identification Network Group (iPING) was developed out of concern for these questions and both the paucity of research and research problems in relation to addressing them.

Myeong Soo Lee - Korea Chin.J.Integr.Med

Terje Alraek - Norway

Chris Zaslowski -Australia

Ju Ah Lee - Korea

Stephen Birch - Holland

Zhao-xiang Bian - China

Nicola Robinson - UK

Tae-Hun Kim - Korea

Mark Bovey - UK

PANEL DISCUSSION

Current Research and Future Directions in Pattern Identification: Results of an International Symposium

Myeong-Soo Lee¹, Ju-Ah Lee¹, Terje Alraek^{2,3}, BIAN Zhao-xiang (字兆祥)⁴, Stephen Birch⁵, Hirozo Goto⁶, Jeeyoun Jung¹, KAO Shung-te (高尚德)⁷, Sang-Kwan Moon⁸, Bong-Ki Park¹, Kyung-Mo Park⁹, Soo-Seong You¹, Kyung-Jin Yun¹, and Chris Zaslowski¹⁰

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

How to develop the evidence for the diagnostic patterns?

Intra-rater and inter-rater reliability studies are VITAL

If the results of a study show poor agreement, it is possible to address this with remedial training until good agreement is achieved [Zhang et al. 2005, 2008] This is ROUTINELY used in training how to use diagnostic tests in many areas in healthcare

While little research has been performed to date on this, possibly significant progress was made with Popplewell's development and validation of a tool for performing TCM based diagnosis [Popplewell et al. 2018] and for identifying the ideal statistical testing procedures for reliability studies [Popplewell et al. 2018]

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 00, Number 00, 2018, pp. 1-9
© Mary Ann Liebert, Inc.
DOI: 10.1089/acm.2018.0065

JACM

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 00, Number 00, 2018, pp. 1-6
© Mary Ann Liebert, Inc.
DOI: 10.1089/acm.2017.0297

JACM

ORIGINAL ARTICLE

A Novel Approach to Describing Traditional Chinese Medical Patterns: The "Traditional Chinese Medical Diagnostic Descriptor"

Michael Popplewell, PhD¹, John Reizes, PhD², and Chris Zaslowski, PhD³

Appropriate Statistics for Determining Chance-Removed Interpractitioner Agreement

Michael Popplewell, PhD¹, John Reizes, PhD², and Chris Zaslowski, PhD³

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

How to develop the evidence for the diagnostic patterns?

An important aspect of developing the evidence includes studies to ENSURE agreed upon descriptions of the patterns and identifying potential bio-psycho-social variations

In 2 recent studies that built on Evidence from China and Korea of poor agreement [Choi et al. 2016, Liao, Wang et al. 2016] we found considerable disagreement on what constitute the signs and symptoms of blood stasis, qi deficiency and qi stagnation in Major literature reviews Birch et al. 2021, 2022]



Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

These studies provided tentative evidence that the patterns may vary in different countries as part of an expected bio-psycho-social variability

They also showed that within Asian and Chinese origin texts there is much variation and within English language texts there is also much variation

Both the issues of lack of agreement where it should occur and identification of bio-psycho-social variations are under-addressed

In another study I showed that heart patterns and the understanding of the concept of shen are different in China and Japan, and Could expose potential reasons for this These findings support the notion of the Bio-psycho-social variations



Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

One way researchers especially in Asia have attempted to get around the problem of lack of agreement is to develop diagnostic tools for the patterns

To do this they follow a process routinely used in **biometric** research for the development of such a diagnostic 'instrument' First selected experts identify what questions to ask, what observations to make

Then they go through stages of testing among the experts until they can agree on a final set of questions, observations, how to score or scale them

Then the 'instrument' needs to be clinically tested on relevant patient populations by relevant practitioners

When the diagnostic 'instrument' is confirmed to reliably give the same results, that practitioners using it get the same results (intra- and inter-reliability) & they confirm that it actually diagnoses the disease/symptom/pattern (validity) THEN it is approved

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

A number of such tools have been developed for some TEAM based patterns (e.g. blood stasis, spleen qi deficiency....)

BUT...our blood stasis review and qi deficiency/qi stagnation review examined such tools for these 3 patterns and also found considerable inconsistency between the different instruments, questionnaires

This inconsistency is unacceptable in medicine

Thus while some progress has been made with this, much more work is needed and for all of the relevant patterns

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

What evidence do we have that using treatment based on the TEAM diagnoses is more effective than not doing that, or even relevant?

Many trials 'say' that they have performed treatment according to the patterns identified in each patient

BUT for this evidence to count it is necessary that the diagnoses are confirmed and agreed upon as being correct (inter-rater agreement)

Essentially guaranteeing inter-rater agreement of the diagnosis becomes an additional 'inclusion criteria' for such a study

One way to do this is for every study that uses TEAM based diagnosis and matched treatment to have 2-3 practitioners examine each patient and only proceed with treatment when they have agreed on the diagnosis (which is matched with a treatment)

Only a handful of studies have done this

Testing what is taught in acupuncture schools and how practitioners treat patients using TEAM/TCM theories and their diagnoses

How to develop the evidence for the clinical relevance of such treatments?

First, guidelines need to be developed and published that describe the steps necessary for clinical trials that use TEAM based diagnosis and treatments to be able to make supportable statements about the role of the TEAM based diagnosis and treatment. Such a guideline has not yet been written – we hope that in the iPING we can work on this now that covid is mostly over.....

Then studies need to be designed to take into account the additional steps and procedures needed to perform such studies. Unfortunately these studies may need large sample sizes and thus could be restricted by access to sufficient funding. The field needs to get involved!!!!

Testing theories of practice

In mainstream medicine treatments are developed first by studying mechanisms of a disease/symptom and what mechanisms could affect them.

Then treatments such as a drug are developed in the laboratory where it is shown to affect the relevant mechanisms, produce relevant effects, what its safety profile is and so on.

Only after these laboratory tests do new treatments get tested in clinical trials.

Thus when the gold standard ‘placebo controlled clinical trial’ or ‘Explanatory trial’ is performed it becomes a kind of glorified test of known mechanism(s) [Birch, Lewith 2007].

There is limited theory-of-the-treatment, that mostly relates to the known mechanisms which are rooted in established anatomy and physiology.

Testing theories of practice

What are the theories of TEAM based acupuncture?

They include e.g. 'meridians', 'acupoints', 'qi', 'yin-yang', 'five-phases' and so on

None of these were developed in laboratories subject to strict testing
They were described 2000 years ago and then zillions of practitioner over time figured out how to use them

It is not even clear that they were intended to describe 'what is' in the same way that science focuses on describing 'what is', rather it described things in ways that permit people to act [Slingerland 2003, Birch et al. 2014]

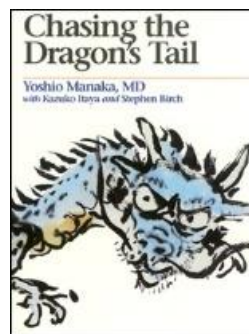
Given the insubstantial nature of these concepts, the HUGE variation in how they have been understood and used how do we start to test them?

Clinical trials are physically incapable of testing them

We do not yet know what laboratory studies are needed

Testing theories of practice

Having worked with Manaka in Japan who developed novel ways of examining and thinking about these traditional ideas
I was inspired to pursue this



I found a mathematician and started with math modelling
Mathematics is a kind of neutral language that permits descriptions of things so that they can be linked to other things and tested
This modelling is VERY COMPLICATED!!!!

We also worked with a physicist from Stanford in the modelling

We developed a model for the 5-phases [Birch, Friedman 1989]

Meridian qi flow/xu&shi [Friedman, Birch Tiller 1989]

And tied this to a generic model of how healing might occur [Friedman, Birch, Tiller 1997]

Testing theories of practice

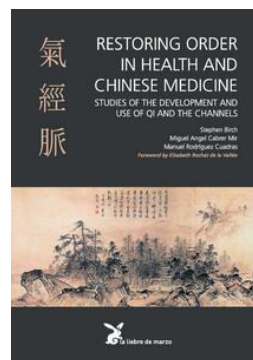
25 years later Friedman and I are developing models for the meridian system, healing, the role of the practitioner, treatment and etc..... Nothing too ambitious!! Hehe

We assume that the traditional concepts/theories are different ways of describing what modern medicine describes

By exploring the dynamics of how things work we develop the math models as translations for the concepts/ theories and their dynamics so that we can start to compare them to known and tested physiology and processes and eventually start to make measurements that would allow us to make statements about the traditional concepts/theories that are NOT dismissed by the scientific community

Testing theories of practice

In my recent co-edited book about the history, development, nature and uses of ‘qi’ and the ‘jingmai’ (meridian) I co-authored a chapter with my friend Mark Bovey describing **9-steps** that are needed in order to perform valid studies of concepts like ‘qi’, ‘meridians’ and so on



Since this was only recently published [Birch et al. 2014] and has not yet been reviewed by the scientific community and no one is using it, we think that NO valid studies have been done yet attempting to measure things like qi, meridians, even acupoints